IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY No S219 of 2012 and S1 of 2013

BETWEEN:

APOTEX PTY LTD ACN 096 916 148
Applicant/Appellant

SANOFI-AVENTIS AUSTRALIA PTY LTD
First Respondent

SANOFI-AVENTIS DEUTSCHLAND GMBH
Second Respondent

AVENTISUB II INCORPORATED
Third Respondent

RESPONDENTS' SUBMISSIONS

Part I: Suitable for publication

1. This submission is in a form suitable for publication on the internet.

Part II: Issues presented by the appeal

2. The appeal raises the following issues concerning the requirement in s 18(1)(a) of the *Patents Act* 1990 (Cth) (the **Act**) that an invention be a "*manner of manufacture within the meaning of section 6 of the Statute of Monopolies*":

   (a) Are "*methods of treatment of the human body*" excluded from patentability because they do not meet that requirement?

   (b) Is the invention claimed in claim 1 of the respondents' Australian Patent No 670491 (the **Patent**), being an invention which on the findings made below is novel, inventive, useful, fully described and the subject of a fairly based claim, excluded from patentability on this basis?

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3. The referred part of the special leave application raises the issue whether such leave should be granted and, if so, whether the Full Court erred in finding that the appellant threatened to infringe the Patent under s 117 of the Act.

Part III: *Judiciary Act* 1903

4. The respondents have considered whether any notice should be given pursuant to s 78B of the *Judiciary Act* 1903 (Cth). In their view this is not necessary.

Part IV: Contested material facts

5. Some of the facts in Part V of the appellant's submissions are irrelevant. Others as stated are incomplete or incorrect as indicated below.

10 6. Contrary to paragraph 8 of the appellant's submissions, the Patent does not state "*that psoriasis is one of a number of medical uses for which Hoechst obtained patent protection for Leflunomide, the first group being claimed in the 341 Patent*". In fact, as Bennett and Yates JJ held:[1]

> *The face of the specification makes clear that the patentee identifies as its invention a new method for preventing or treating a skin disorder, specifically psoriasis. There is nothing on the face of the specification that would suggest that the invention there described is devoid of the necessary quality of inventiveness to sustain a valid patent.*

7. Moreover, as both their Honours and the trial judge held:[2]

20 > *The qualities of leflunomide (or its character), on the face of the patent in suit, also could not be described as "known" in the sense that [that] term is used in this context. It is true that the patent in suit discloses leflunomide as being anti-inflammatory, but that general description cannot be said to exhaustively define the actions and thus the characteristics or qualities of leflunomide. This is consistent with the position disclosed by the objective evidence available at that time ...*

8. Paragraph 9 of the appellant's submissions does not fairly set out the statement of indications in the appellant's product information (**PI**) document:[3]

> ***INDICATIONS***
>
> 30 *Apo-Leflunomide is indicated for the treatment of:*
>
> - *Active Rheumatoid Arthritis.*
> - *Active Psoriatic Arthritis. Apo-Leflunomide is not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease.*

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[1] [2012] FCAFC 102 at [195].
[2] [2011] FCA 846 at [242]; [2012] FCAFC 102 at [195].
[3] [2011] FCA 846 at [62], [261]; [2012] FCAFC 102 at [138].

9. In context, this instructed doctors to use the product for the treatment of psoriasis associated with psoriatic arthritis (**PsA**).[4] There was evidence of a relationship between PsA and psoriasis, and it was known that a person with PsA would almost always have or develop psoriasis.[5] Further, the PI document itself reported on the efficacy of leflunomide for the treatment of psoriasis.[6]

10. In relation to paragraph 10 of the appellant's submissions, there was no evidence of the appellant's "*intention*" to supply leflunomide for particular treatments other than its PI document, which conveyed the above instructions. The interlocutory orders did not restrain the appellant from <u>any</u> supply of its product, but rather supply in circumstances where the appellant had reason to believe that the product may be used for the treatment of PsA.[7]

11. The facts in paragraph 12 of the appellant's submissions do not fully reflect the findings made in relation to leflunomide and its use in the treatment of psoriasis. Leflunomide was prescribed by rheumatologists for the treatment of PsA. The evidence indicated that "*rheumatologists ... do seek, and will seek, to treat both conditions when patients present with PsA and psoriasis concurrently*" and that the administration of leflunomide to such a patient "*would be expected also to prevent or treat the patient's psoriasis, to some extent at least*".[8]

12. As to paragraph 13 of the appellant's submissions, the appellant attacked the validity of the Patent on the grounds that the invention was not novel, did not involve an inventive step, was not a manner of manufacture and was not useful; that the specification did not fully describe the invention; and that the claim was not fairly based on that description. Each of those attacks was rejected by the trial judge and, to the extent raised on appeal, by the Full Court.[9]

13. In relation to paragraph 14 of the appellant's submissions, the reservation by the appellant of its right to "*dispute the patentability of methods of treatment*" had an important qualification: its abandonment of any reliance on the ground that such monopolies are "*generally inconvenient*" according to the proviso in s 6 of the *Statute of Monopolies* 1623. The appellant had particularised such a ground but deleted it by amendment shortly before trial.[10] The respondents made it plain at the time that this could impact on the evidence to be adduced at

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[4] [2011] FCA 846 at [262]; [2012] FCAFC 102 at [144]-[145].
[5] [2011] FCA 846 at [126]; [2012] FCAFC 102 at [6], [95].
[6] [2012] FCAFC 102 at [144].
[7] Paragraph 1 of orders dated 30 October 2008.
[8] [2012] FCAFC 102 at [150]-[154].
[9] [2011] FCA 846 at [227], [235], [243], [246], [253], [258]; [2012] FCAFC 102 at [67], [183], [197].
[10] Appellant's Further Amended Particulars of Invalidity dated 7 March 2011.

trial.[11] In the event, no evidence was adduced in relation to that ground, and the appellant did not seek to make out any case based on "*general inconvenience*". As Keane CJ noted on appeal, the appellant eschewed any reliance on the ground before the Full Court.[12] The appellant did not seek to rely on the ground in support of its application for special leave to appeal.

14. Finally, in relation to paragraph 15 of the appellant's submissions, the appellant accepted in the Full Court that if no error was demonstrated in relation to the trial judge's findings concerning the application of s 117(2)(b) or (c) of the Act, then s 117(1) was correctly engaged against the appellant.[13]

10 **Part V: Applicable provisions**

15. The appellant has proposed that copies of relevant provisions be provided in an agreed book.[14] The respondents anticipate that this will be agreed.

Part VI: Argument on appeal

Introduction

16. The Patent claims a "*method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of ... [leflunomide]*".[15] Given the unchallenged findings made below, the appeal is to be conducted on the basis that that method is novel and involves an inventive step over the prior art before the priority date of the
20 Patent, that the method is useful and fully described in the specification, and that the claim is clear and fairly based on that description.[16]

17. In these circumstances, there is no sound basis for concluding that the method claimed in the Patent is not a patentable invention. The appellant's submissions require the recognition of a special exclusion from that concept in relation to methods of human treatment. As explained below, the wording and context of the Act provide no basis for such an exclusion. Decisions of this Court do not support it. A strong line of authority in the Federal Court provides clear and compelling reasons against it. When one analyses the bases for exclusion put forward by the appellant, it becomes apparent that there are numerous

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[11] Transcript of hearing before Jagot J on 7 March 2011, T 18.1-10.
[12] [2012] FCAFC 102 at [23].
[13] [2012] FCAFC 102 at [146].
[14] Appellant's submissions, para 77.
[15] [2012] FCAFC 102 at [107]; see also [2]-[3]; [2011] FCA 846 at [3]-[4], [103].
[16] See ss 18(1) and 40(2) and (3) of the Act.

difficulties standing in the way of the recognition of any such exclusion, and in particular its application to the method claimed in the Patent.

18. As Bennett and Yates JJ observed below, the patentability of methods of treatment represents "*orthodoxy in Australian patent law*".[17] Both before and since the Act was passed, it was and has been commonplace for patents to be granted for methods of treatment.[18] The legislature had the clear opportunity in passing the Act specifically to exclude such methods. It did not do so. The appellant invites the Court to graft onto the legislation an implied exclusion that was plainly never intended. That invitation should not be accepted.

10 ***The statutory framework***

19. Section 18 of the Act sets out the requirements for a patentable invention. For a standard patent these include, in s 18(1)(a), that the invention so far as claimed in any claim "*is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies*". Section 18(1A)(a) imposes the same requirement in relation to innovation patents. See also the definition of "*invention*" in Schedule 1 to the Act, which provides that "***invention*** *means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention*".

20. The Act does not further define a "*manner of manufacture within the meaning of*
20 *section 6 of the Statute of Monopolies*". For that purpose, it is necessary to go to the cases. It has long been clear that the concept includes methods or processes as well as products.[19] However, prior to the decision of this Court in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, it had been held that a method was not a "*manner of manufacture*" unless it resulted in, or had some material effect on, a "*vendible product*".[20] The decision in *NRDC* clarified that requirement, holding that it was sufficient that a method result in an "*artificially created state of affairs*" of "*economic utility*".[21] As submitted below, this paved the way for the recognition that methods of human treatment are patentable inventions.

30 21. In any case, it is clear from the wording and context of the Act that the concept of "*manner of manufacture*" includes methods of human treatment.

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[17] [2012] FCAFC 102 at [193].

[18] [2012] FCAFC 102 at [193]; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 17G; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [16].

[19] *Boulton v Bull* (1795) 2 H Bl 463; 126 ER 651.

[20] *Re GEC's Application* (1942) 60 RPC 1.

[21] *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 277.

22. First, consistently with the decision in *NRDC*, the Act indicates that the notion of an "*invention*" extends to methods or processes, as well as products: see sub-paragraph (b) of the definition of "*exploit*" in Schedule 1 to the Act. See also the definition of "*patented process*" in Schedule 1, and s 121A, which addresses proof of infringement in relation to a "*patent for a process*".

23. Secondly, the succeeding subsections of s 18 set out some express exclusions from the concept of a "*patentable invention*" as follows:

> *(2) Human beings, and the biological processes for their generation, are not patentable inventions.*
>
> *(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.*
>
> *(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.*

24. The section thus proceeds on the basis that subject matter of the kind identified could otherwise constitute a "*patentable invention*", and in particular a "*manner of manufacture*" within the meaning of s 18(1)(a). Yet while "*[h]uman beings, and the biological processes for their generation*" are expressly excluded, there is no exclusion of methods of treatment of the human body.

25. This is significant because, as submitted above, it is commonplace for patents to be granted that include claims to methods of treatment. That practice was "*long established*" when the Act was introduced in 1990,[22] and it is a practice of which Parliament must be taken to have been aware. The validity of the practice has since been affirmed by the Full Court of the Federal Court on two occasions – three including this case. During that period, the Act has been amended more than 20 times.[23] As Keane CJ observed below, one cannot attribute to Parliament the intention to deny patentability to methods of treatment given the ample opportunity it has had to do so.[24]

26. It will be noted that s 18(2) was in the Act when it was passed, while s 18(3) and (4) were added in 2001, after the decisions of the Full Court in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 and *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524, which upheld the patentability of methods of treatment. It is well-settled that legislation is to be construed having regard to the context in which it was enacted.[25]

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[22] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 17G.
[23] Most recently by the *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012 (Cth).
[24] [2012] FCAFC 102 at [26].
[25] *Network Ten Pty Ltd v TCN Channel Nine Pty Ltd* (2004) 218 CLR 273 at [11]-[12].

27. Thirdly, other provisions contemplate that patents may be granted for methods of treatment. Thus s 119A establishes an exemption from infringement of a "*pharmaceutical patent*" for the purpose of obtaining regulatory approval of pharmaceuticals. In this context, s 119A(3) defines a "*pharmaceutical patent*" as including "*a patent claiming ... a method, use or product relating to a pharmaceutical substance*". See also the definition of "*pharmaceutical substance*" in Schedule 1. The extension of term provisions in Part 3 of Chapter 6, which apply to pharmaceutical substances *per se*, allow that pharmaceutical patents may extend to other "*form[s] of the invention*": see s 78(b).[26] Such other forms of the invention and methods or uses relating to pharmaceutical substances plainly capture methods of treatment of the human body. These provisions are clearly inconsistent with the appellant's contention.

28. Finally, there is nothing in the extrinsic material to indicate that methods of treatment were intended to be excluded by the Act. What is clear is that Parliament intended to retain the existing threshold test of patentability based on the concept of "*manner of manufacture*".[27] As noted in *Rescare*, the practice of the Commissioner of Patents at that time was recorded in the July 1984 edition of the *Patent Examiner's Manual*. The manual stated, after referring to the doubts expressed by Barwick CJ in *Joos v Commissioner of Patents* (1972) 126 CLR 611 concerning the basis for excluding methods of treatment:[28]

> *In view of the doubts expressed by Barwick CJ, and his statement that ... the Commissioner ought only to refuse to proceed with an application if on no reasonable ground could what it claims be said to be within the Statute, ... no objection is to be taken to methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved.*

29. This was the context in which the Act was introduced. Moreover, consideration of the case law before and after 1990 does not support any different result.

The High Court cases

30. Contrary to the appellant's submission, neither *NRDC* nor this Court's earlier decision in *Maeder v Busch* (1938) 59 CLR 684 held that methods of human treatment were not, or were "*probably not*",[29] patentable inventions.

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[26] See also Explanatory Memorandum, *Intellectual Property Laws Amendment Bill* 1997 (Cth), p 18 (notes on clauses, para 10), referring to "*claims to ... new methods of using pharmaceutical substances where the substances themselves are already known*".

[27] Report of the Industrial Property Advisory Committee, "Patents, Innovation and Competition in Australia, 29 August 1984, p 40; quoted in appellant's submissions, para 31.

[28] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 234.

[29] Appellant's submissions, para 17.

31. In *Maeder*, which involved a process for treating human hair, the question was expressly left undecided. Latham CJ held that the point was "*so important and possibly so far-reaching, that it is wise to abstain from deciding it until the necessity for doing so arises*".[30] Dixon J "*prefer[red] to leave undecided the question whether a process for treating the hair may be patentable*".[31] Evatt J held that the point need not be decided, but was inclined not to recognise any general exclusion.[32] McTiernan J held that it was "*unnecessary to resolve the doubt whether the process specified falls within this conception*".[33]

32. In *NRDC*, the Court was not concerned with a method of treatment of the human body, but rather a method of using a known chemical substance to treat crop areas in order to eradicate and control weeds from such areas without affecting the crops themselves. This was held to be a "*manner of manufacture*", notwithstanding the absence of any "*vendible product*":[34]

> *The effect produced by the appellant's method exhibits the two essential qualities upon which "product" and "vendible" seem designed to insist. It is a "product" because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic; for it provides a remarkable advantage, indeed to the lay mind a sensational advantage, for one of the most elemental activities by which man has served his material needs, the cultivation of the soil for the production of its fruits. ... It achieves a separate result, and the result possesses its own economic utility consisting in an important improvement in the conditions in which the crop is to grow, whereby it is afforded a better opportunity to flourish and yield a good harvest.*

33. The Court's earlier, tentative remarks to the effect that "*methods of surgery and other processes for treating the human body may well lie outside the concept of invention*" and "*apparently must be put aside*" did not reflect any determination that such methods are not patentable.[35] The Court did not, and did not need to, engage in any reasoning on that question. In any case, it is by no means clear that the "*methods of surgery and other processes*" referred to by the Court extend to methods of the kind claimed in claim 1 of the Patent.

34. The approach of Barwick CJ in *Joos* is instructive. That case involved a method for the treatment of human hair and nails. His Honour observed that *Maeder* did not decide whether such methods were patentable and noted that some of the

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[30] *Maeder v Busch* (1938) 59 CLR 684 at 699.
[31] *Maeder v Busch* (1938) 59 CLR 684 at 707.
[32] *Maeder v Busch* (1938) 59 CLR 684 at 707.
[33] *Maeder v Busch* (1938) 59 CLR 684 at 708.
[34] *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 277.
[35] *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 270, 275.

assumptions on which the Court had proceeded in that case were "*very questionable*" in light of the Court's subsequent decision in *NRDC*.[36] Of the "*economic utility*" requirement of *NRDC*, his Honour said:[37]

> *The national economic interest in the product of good surgery – and therefore in the advancement of its techniques – if in no other respect than the repair and rehabilitation of members of the work force, including management in that grouping, is both obvious and may be regarded as sufficiently proximate, in my opinion, as to be capable of satisfying the economic element of an invention, if other elements are present and no impediments exist to the grant. One has only to recall the economic impact of workers' compensation, invalid pensions and repatriation costs to recognise that proximity.*

35. Importantly, in both *NRDC* and *Joos*, it was the outcome or result of the method that had the necessary "*economic utility*", not the method itself.

36. Barwick CJ noted that the reference in *NRDC* to methods of treatment had been "*no more than a passing reference not intended to be definitive*".[38] His Honour did not find it necessary, in deciding the case, to determine whether methods of treatment were excluded. His Honour said that any such exclusion should be narrowly defined and held that the method in suit could be distinguished as it was merely a cosmetic process.[39] His Honour also said:[40]

> *If I had to do so, as at present advised, I would place the exception, if it is to be maintained, on public policy as being, in the language of the Statute of Monopolies, "generally inconvenient" ...*

37. His Honour thus located the basis for any exclusion of methods of treatment, if there was to be one, in the ground of "*general inconvenience*", as opposed to the subject matter being "*non-economic*". This is consistent with the view later expressed in *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171, where the majority said that the "*classification of certain methods of treatment of the human body as an inappropriate subject for grants under the Act appears to rest on this footing*", citing *Joos*.[41] Again, this did not reflect any determination that such methods are not patentable. The use of the expression "*certain methods of treatment*" will also be noted.

38. As such, no decision of this Court has held that methods of treatment of the human body are not patentable. Moreover, recent observations have seen the

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[36] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 617-618.
[37] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618.
[38] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618.
[39] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618-619, 622.
[40] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 623.
[41] *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171 at [34].

exclusion, if there is to be one, as resting on the ground of "*general inconvenience*" – a ground not open to the appellant in this case.

The Federal Court cases

39. By contrast, the question has received detailed consideration at the Federal Court level, where methods of treatment have been held to be patentable inventions. The respondents respectfully submit that the reasoning in those cases is compelling and should be accepted by this Court.

40. In *Rescare* at first instance, Gummow J held that a method for treating sleep apnoea was patentable. His Honour surveyed the cases and observed that the point had not been decided in either *Maeder* or *NRDC*.[42] His Honour accepted that any exclusion, if it was to be recognised, would have to be based on the ground of "*general inconvenience*".[43] His Honour declined to do so, referring to the practice of granting patents for methods of treatment as a circumstance that distinguished the position in Australia from that in other countries.[44]

41. On appeal, Lockhart J reviewed the authorities in detail, concluding like Gummow J that the High Court had not determined the question. Importantly, his Honour dealt with two independent bases on which the challenge to the patentability of such methods was brought: the principles developed in *NRDC* (the "*right question*" advocated by the appellant in this case[45]); and that of "*general inconvenience*".[46] Both arguments were rejected.

42. As Lockhart J observed, once the approach in *NRDC* is accepted, there is no logical basis for distinguishing between the patentability of products for use in treatment and the patentability of methods of treatment involving the use of such products. His Honour also had regard to the express exclusion in s 18(2) of the Act, which does not apply to methods of treatment.[47] Wilcox J agreed with Lockhart J and amplified the point regarding s 18(2):[48]

> *Parliament has never excluded a method of human medical treatment from patentability or the definition of "invention"; not even in the recent statute, the Patents Act 1990 (Cth) ..., that revised Australian patent law and made a specific provision (s 18(2)) dealing with the patentability of human beings and the biological processes for their generation. ... in the face of apparently deliberate decisions by Parliament not to build*

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[42] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 236.
[43] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 237.
[44] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 239.
[45] Appellant's submissions, para 16.
[46] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 16-19.
[47] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 17, 19.
[48] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 42-43.

> *this particular exclusion into its legislation, courts should be hesitant to introduce the exclusion by reference to those very general principles.*

43. Wilcox J also pointed out that *Maeder*, *NRDC* and *Joos* "*assumed (rather than decided) that there was a special rule*" for methods of treatment.[49]

44. *Bristol-Myers* concerned a method of treatment involving the administration of the drug taxol and in that sense was analogous to the present case. Referring to *Rescare*, Black CJ and Lehane J followed what they called "*the only substantial consideration of this important question in Australia, prior to its consideration in the present case*" and "*a close and persuasive analysis of principle and authority*".[50] Their Honours were fortified by two matters:[51]

> *The first of these is what seems to us to be the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment ... This seems particularly the case where, as here, the claim is for an invention for the administration of a product. ... The second compelling consideration is the very limited extent to which the Parliament dealt with patents with respect to the human body when it enacted the 1990 Act, bearing in mind, too, that it did so at a time when the long-standing practice in Australia was (as we are informed it still is) to grant patents for methods of medical treatment of the human body.*

45. Finkelstein J agreed in the result. His Honour also considered both bases for the challenge to patentability and rejected each of them.[52]

46. The Full Court in the present case correctly followed *Rescare* and *Bristol-Myers*. Keane CJ referred to the "*ample opportunity afforded to the Parliament on the occasions when it has amended the Act to legislate to deny that methods of medical treatment of human ailments are patentable*", and said:[53]

> *There is now even more force in the views expressed by Lockhart and Wilcox JJ in [Rescare] that one cannot attribute to the Parliament the intention that the area of non-patentability of inventions associated with the preservation of the health of human beings is wider than the express statement of non-patentability in relation to "human beings, and the biological processes for their generation", in s 18(2) of the Act.*

47. Similarly, Bennett and Yates JJ described the patentability of methods of medical treatment as "*representing orthodoxy in Australian patent law*", and referred to it being "*commonplace for patents to be granted in Australia that*

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[49] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 44.
[50] *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [13], [15].
[51] *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [15]-[16].
[52] *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [128]-[142].
[53] [2012] FCAFC 102 at [26].

include claims for methods of medical treatment".[54] Their Honours also emphasised the significance of the wording of s 18 of the Act.

48. In the Full Court in *Rescare*, Sheppard J upheld the exclusion of methods of treatment of the human body on the ground of "*general inconvenience*",[55] and his Honour's dissenting judgment was followed by Heerey J at first instance in *Bristol-Myers*.[56] For the reasons given below, neither judgment is correct. In any event, this ground is not propounded by, or open to, the appellant.

No exclusion on "non-economic" ground

49. The appellant argues that methods of treatment should be excluded from patentability on the ground that they are "*non-economic*".[57] As explained above, no decision of this Court or the Federal Court has upheld any exclusion on this basis. The argument should be rejected for the following reasons.

50. First, there is nothing in the wording or context of the Act to support the proposition that methods of human treatment are in any sense "*non-economic*". To the contrary, as submitted above, the references in s 18(2) to biological processes for the production of human beings, and in s 119A(3) to methods and uses relating to pharmaceutical substances, strongly suggest that Parliament regarded any requirement of "*economic utility*" as being satisfied by such methods or processes when those provisions were introduced. Otherwise, there would have been no need for these express exclusions.

51. Secondly, it cannot sensibly be concluded that methods of treatment generally, and the method in this case in particular, are "*non-economic*". Given the way the appellant conducted its case, the respondents did not have the opportunity to adduce evidence specifically directed to this issue. Nevertheless, the evidence showed that, prior to the invention claimed in the Patent, treatments for psoriasis were time-consuming and inconvenient and in some cases had potentially life-threatening side effects. The invention avoided the need for such therapies, reducing unproductive time for the patient and the involvement of medical professionals and, indeed, fatalities.[58] The potential cost savings to the patient, the general community and the public health system can hardly be said to be "*non-economic*".[59] The effect here is no less "*economic*" than that recognised in *NRDC*, where the utility of the claimed method resided in the

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[54] [2012] FCAFC 102 at [193].
[55] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 41.
[56] *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (1998) 41 IPR 467 at 480-482.
[57] Appellant's submissions, paras 22-25.
[58] Affidavit of Dr Shumack dated 26 November 2009, paras 11-27.
[59] See the comments of Barwick CJ in *Joos*, extracted in para 34 above.

"*improvement in the conditions in which the crop is to grow, whereby it is afforded a better opportunity to flourish and yield a good harvest*".[60]

52. Contrary to the appellant's submission, recognition of methods of treatment as patentable does not depend on "*the mere identification of an economic context at the margins of an alleged invention*".[61] Methods of treatment are not relevantly distinguishable from the method in *NRDC*, or many other patentable methods, in this regard. This is not a "*mere scheme*" of the kind considered in *Grant v Commissioner of Patents* (2006) 154 FCR 62. To the extent that the appellant asserts a "*reluctance of human beings to regard an improvement in, say, the state of the psoriasis from which they suffer, as an artificial effect of economic utility rather than an alleviation of their suffering*",[62] there is no evidence of this, and the distinction sought to be drawn is elusive.

53. Thirdly, the appellant's "*non-economic*" criterion provides no rational basis for drawing a distinction between products for treating the human body, such as pharmaceutical products, and methods of treatment. Such a distinction is essential for the appellant's case, for it is not suggested that there is any doubt that a product such as leflunomide may be patentable. As outlined above, the impossibility of supporting any such distinction formed an important part of the reasoning in the judgments in *Rescare* and *Bristol-Myers*.

54. Fourthly, in order to be upheld, any principle for the exclusion of methods of treatment would have to be capable of precise definition. The principle propounded by the appellant is not. What, precisely, constitutes a "*method of treatment of the human body*" for this purpose? Is it limited to "*methods of surgery*", which it may be noted were the only kind of method of treatment specifically identified in the Court's remarks in *NRDC*?[63] Does it extend to methods involving the administration of prescribed pharmaceutical products, as in this case? Is it necessary to distinguish between "*cosmetic*", "*prophylactic*" and "*therapeutic*" methods of the kind discussed in *Joos*?[64]

55. The present case demonstrates these difficulties. The claim is to a "*method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis*", a non-life-threatening condition leading to "*demarcated, red scaly plaques*" on the patient's skin.[65] Different views might reasonably exist as to whether the

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[60] *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 277.
[61] Appellant's submissions, para 24.
[62] Appellant's submissions, para 24.
[63] *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 275.
[64] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 623.
[65] Affidavit of Dr Shumack dated 23 October 2008, paras 18, 28.

amelioration of such skin abnormalities, or their prevention, is cosmetic rather than therapeutic in nature. Such views might well change over time.

56. An example given by Barwick CJ in *Joos* further illustrates the point:[66]

> *Those who apply chemical preparations to the skin to prevent sunburn in climates which enjoy sunshine and moderate air temperatures can scarcely be regarded either as, in a relevant sense, treating their bodies or as undergoing treatment. On the other hand, the application to the skin of an ointment designed and effective to remove keratoses from the skin would be an instance of medical treatment.*

10 57. It is questionable whether the first part of this statement would reflect current opinion today, given the problems associated with the depletion of the ozone layer and the heightened recognition of the risk of skin cancer absent protection from the sun. At any rate, there is no warrant for regarding his Honour's first example as "*economic*", and the second as "*non-economic*", and excluding only the latter from patentability on this basis. Another illustration relates to the appropriate characterisation of methods of contraception, which have been held not to be "*methods of medical treatment*" in the United Kingdom.[67]

58. Fifthly, in addressing what is in truth a policy argument, it is necessary to have regard to the ramifications that would flow from its acceptance. The effect of the
20 appellant's case is that no patent could be granted for a method involving a therapeutic use of a pharmaceutical substance, even if that method is novel, inventive, useful and fully described, and otherwise satisfies the requirements of the Act, as in this case. There would be no economic incentive for the development of new therapeutic uses after identification of the substance *per se*. The policy of the Act in providing an incentive for the stimulation of research into the development of new treatments would be undermined.

59. Sixthly, the Act otherwise requires that an invention be "*useful*",[68] meaning that it must work, including in accordance with any promise in the specification.[69] This suggests nothing as to whether there is a relevant market for the invention
30 or whether its working will be "*economic*" in the sense contended for by the appellant. It would be wrong to graft on such an additional requirement. As noted above, the invention was held to be useful in this case.

60. Finally, as the Court observed in both *NRDC* and *Maeder*, a widening conception of the notion of a "*manner of manufacture*" has been a characteristic

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[66] *Joos v Commissioner of Patents* (1972) 126 CLR 611 at 618.
[67] *Schering AG's Application* [1971] RPC 337 at 342.
[68] Section 18(1)(c) of the Act.
[69] See *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 81 ALR 79 at 96.

of the growth of patent law.[70] If, contrary to the above submissions, methods of treatment were once properly regarded as "*non-economic*", that is no longer the case. This is reflected in the recognition in *Joos* and *Advanced Building* that any exclusion would have to be based on "*general inconvenience*".

No exclusion on "general inconvenience" ground

61. The appellant says it does not "*formally abandon*" the ground of "*general inconvenience*", although it does not seek to support that approach.[71] As has been explained, the appellant did formally abandon the point below. Had the point been run it may, and probably would, have impacted on the evidence to be adduced. Accordingly, the point is not open to the appellant.[72]

62. It should be noted that a number of the matters raised by the appellant under the guise of "*economic utility*" in fact raise policy considerations that could only be properly considered, if they can be considered at all, under the rubric of "*general inconvenience*". The appellant's assertion as to the undesirability of affecting the judgment of surgeons or physicians is an example.[73]

63. If, contrary to the above, the appellant is permitted to rely on this ground, it should not be accepted as a basis for excluding methods of treatment from patentability. Many of the points made above apply, including those regarding the statutory context, the absence of any logical distinction between products and methods, the impossibility of precise definition, the adverse ramifications and the widening notion of what is patentable.[74] The respondents also rely on the reasons in *Rescare* and *Bristol-Myers* which held against the exclusion of methods of treatment on the basis of "*general inconvenience*".[75]

64. In addition, to the extent that any finding of "*general inconvenience*" requires an acceptance that the grant of patents for methods of human treatment would have some deleterious effect, there is no evidence of this. In particular, there is no evidence that the Patent has had such an effect. The existence of the "*long established*"[76] practice of granting patents for methods of treatment in Australia

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[70] *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 269-270; *Maeder v Busch* (1938) 59 CLR 684 at 706.

[71] Appellant's submissions, para 30.

[72] See para 13 above; *Coulton v Holcombe* (1986) 162 CLR 1 at 7-8.

[73] Appellant's submissions, paras 25, 37; see also para 31.

[74] See paras 22-28 and 53-60 above.

[75] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 233-239; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 6-19, 42-45; *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [7]-[18], [99]-[142].

[76] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 17G; see also [2012] FCAFC 102 at [193]; *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [16].

strongly suggests that there is no such effect. The point was made by Jacob J in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, speaking of the exclusion of such methods in the *Patents Act* 1977 (UK):[77]

> *The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment. It is noteworthy that in the U.S. any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble.*

10 65. Further, it is by no means clear from first principles why such monopolies should be "*generally inconvenient*". In *Bristol-Myers*, Finkelstein J noted the positive consequences that flow from the grant of patents for methods of treatment.[78] In *Schering AG's Application* [1971] RPC 337, Whitford J said that "*if the results of such research cannot be protected, individuals and companies are unlikely to undertake it and it is the public who will suffer because they will not be taught new methods of applying known compounds that could bring them great benefit*".[79] To the extent that there are competing policy contentions, a Court is not well placed to resolve them, particularly without evidence.[80]

66. Finally, the respondents respectfully submit that "*general inconvenience*" is not
20 a valid ground of objection in any event, given the terms of s 18 of the Act and its interrelationship with the proviso in s 6 of the *Statute of Monopolies*. This is apparently acknowledged by the appellant in its submissions.[81]

No exclusion on "second medical use" ground

67. The appellant seeks to advance an alternative argument, that methods of treatment of the human body are not patentable if they involve a "*second or subsequent use of a previously known product*".[82] The underlying rationale, as put by the appellant, is that "*an invention limited by purpose is not patentable*".[83] For the following reasons, this argument should not be accepted.

68. First, it represents a veiled attempt to re-agitate grounds of invalidity on which
30 the appellant failed and did not appeal or seek special leave to appeal. As noted above, both the trial judge and the Full Court held that the invention was novel. The trial judge held that it involved an inventive step. The trial judge also

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[77] *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253 at 274.
[78] *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [139].
[79] *Schering AG's Application* [1971] RPC 337 at 340.
[80] *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524 at [140]-[141].
[81] Appellant's submissions, para 30.
[82] Appellant's submissions, paras 2, 46-53.
[83] Appellant's submissions, para 51; see also para 48.

rejected the appellant's contention that the specification on its face disclosed no invention, and this too was upheld by the Full Court.[84] Any impact on the validity of the Patent arising out of its being for a so-called "*second medical use*" was to be addressed, if at all, under these grounds.

69. Secondly, the appellant's argument is the opposite of the contention it sought and obtained leave to bring before the Full Court. Its contention below was that "*methods of medical treatment for a 'second or later medical use' not limited by the purpose of the treatment are not patentable inventions*" (emphasis added).[85] It now seeks to argue that such methods are not patentable because they are limited by purpose.[86] It should also be noted that it was the appellant who advocated for a construction of the claim that was limited by the purpose of the treatment, a construction the Full Court in substance accepted.[87]

70. Thirdly, the argument fails in any event. Section 18(1) directs attention to "*the invention, so far as claimed in any claim*".[88] As noted above, the claim defines a "*method of preventing or treating ... psoriasis, which comprises administering to a recipient an effective amount of ... [leflunomide]*".[89] The claim itself makes no reference to any "*second medical use*". What is claimed is a method of treatment of a particular disorder. Further, there is nothing on the face of the specification to suggest that the characteristics or qualities of leflunomide were relevantly known or that what was claimed was in fact a "*second medical use*". The trial judge's findings to that effect were affirmed by the Full Court.[90] Her Honour also held that what was disclosed in the specification was consistent with the objective evidence.[91] There was no evidence that leflunomide had been used in any form of treatment before the priority date.

71. The passages in the specification referring to leflunomide, relied on by the appellant,[92] do not affect the construction of the claim. The claim would be in the same form in any event. The appellant's "*second medical use*" argument provides no basis for distinguishing between the patentability of methods of treatment involving the administration of previously known products and methods of treatment involving the administration of new products.

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[84] [2011] FCA 846 at [242]; [2012] FCAFC 102 at [195].
[85] [2012] FCAFC 102 at [23], [187].
[86] Appellant's submissions, paras 48, 50-51.
[87] [2012] FCAFC 102 at [37], [40], [125]-[128].
[88] See *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1 at [18].
[89] [2012] FCAFC 102 at [107].
[90] [2012] FCAFC 102 at [195]-[196].
[91] [2011] FCA 846 at [242]; see also [27], [42], [53], [307].
[92] Appellant's submissions, para 46.

72. Contrary to the appellant's submission, the Full Court's construction does not compel any inquiry into the subjective purpose or "*state of mind*" of the medical practitioner. All members of the Full Court expressly indicated the contrary.[93] Rather, the construction requires an objective assessment to be made of the object or end in view of the medical practitioner in prescribing or administering leflunomide for the treatment of the patient. The construction provides no basis for holding that the invention is not a "*manner of manufacture*".

Overseas jurisdictions

73. The overseas cases provide little assistance. They were decided in the context of different legal regimes and in different economic and other circumstances. As Gummow J held in *Rescare*, the established practice of granting patents for methods of human treatment in Australia is a circumstance that "*marks off the Australian experience*" from the position in other countries.[94]

74. The position is starkly different in the United Kingdom, where the legislation explicitly excludes methods of human treatment.[95] This is plainly based on policy grounds rather than any consideration of the inherent requirements for patentability under the *Statute of Monopolies*, which ceased to be relevant with the passing of the current statute. Further, the legislation contemplates that, *in lieu* of methods of treatment, substances "*for use in any such method*" are patentable.[96] That legislative device is not needed in Australia. The position in continental Europe similarly does not assist the present analysis.

75. The position in the United States is that methods of treatment are patentable. The limited infringement exception referred to by the appellant is irrelevant.[97] It applies to both products and methods and does not deny – indeed it confirms – the patentability of such subject matter. In Canada and New Zealand, while methods of treatment are not themselves patentable, claims to products for use in particular treatments, or "*Swiss-form*" claims, are permitted.[98]

76. One point that can be made is that, in all of the key overseas jurisdictions, the invention claimed in the Patent would be patentable, either directly as a method of treatment or through one or more of the devices referred to above.

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[93] Appellant's submissions, para 25, 50-52; [2012] FCAFC 102 at [40], [126].
[94] *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 239.
[95] *Patents Act* 1977 (UK) s 4A(1)(a); Explanatory Notes to the *Patents Act* 2004 (UK), paras 16-17.
[96] *Patents Act* 1977 (UK) s 4A(2); appellant's submissions, para 56.
[97] Appellant's submissions, para 60; 35 USC § 271(e)(2).
[98] *Apotex Inc v Wellcome Foundation Ltd* (2000) 21 CPR (4th) 499 at [49]-[50]; *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529 at [65]; *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 at [4], [43], [51]-[64], [123].

Infringement under s 117

77. Special leave should be refused on the s 117 point. The application raises no point of principle. It turns upon questions of fact peculiar to this case, the answers to which are in any event dictated by concurrent findings of fact made by the trial judge and the Full Court. It raises no question of the construction of s 117 of the Act, which was recently addressed by this Court.[99]

78. The appellant characterises the "*issue*" as whether it had "*reason to believe*" that doctors would use its leflunomide product in the claimed method for the purposes of s 117(2)(b).[100] This reflects only one of two independent bases on which infringement was established below: both the trial judge and the Full Court also held that s 117(2)(c) was also engaged, because the appellant had given instructions for the use of its product to treat psoriasis.

79. The challenge is unsustainable on both counts. In each case, it represents an attempt to attack the factual findings of the trial judge and the Full Court which are determinative against the appellant. This is exposed by the appellant's invitation to this Court to enter into the debate (resolved against it at both levels below) as to how its PI document should be construed and what characterisation should be placed upon the expert evidence.

80. The appellant implies that its case turns upon the construction of the "*double negative*" in its PI document. This is incorrect. As noted above, the document in terms gave instructions for the use of the appellant's product to treat psoriasis associated with PsA. Aside from the statement of indication, which was clear enough, there was a relationship between PsA and psoriasis; it was known that a person with PsA would almost always have or develop psoriasis; and the PI document reported on the efficacy of the use of leflunomide for the treatment of psoriasis.[101] Moreover, rheumatologists would in fact use the product to treat their patients' psoriasis.[102] As Bennett and Yates JJ said:[103]

> *Apotex's product information – effectively stating that its intended leflunomide product was indicated for the treatment of psoriasis associated with manifestations of arthritic disease – cannot be read as an arid instruction that is unrelated to an acknowledged reality that rheumatologists ... do seek, and will seek, to treat both conditions when patients present with PsA and psoriasis concurrently.*

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[99] *Northern Territory v Collins* (2008) 235 CLR 619.
[100] Appellant's submissions, para 66.
[101] [2011] FCA 846 at [126], [262]; [2012] FCAFC 102 at [6], [95], [144]-[145].
[102] [2011] FCA 846 at [129]-[130]; [2012] FCAFC 102 at [6], [96].
[103] [2012] FCAFC 102 at [154].

81. These findings are fatal to the appellant's case on s 117. The appellant gave instructions for the use of its product to treat psoriasis and had reason to believe that the product would be so used.

82. Again, contrary to the appellant's submission, the Full Court did not decide the issue based on the subjective purpose or "*state of mind*" of the prescribing practitioner, or of the witnesses who gave evidence.[104] The Court considered the available evidence in order to form a view as to how rheumatologists would act on the instructions in the PI.[105] To the extent that there was any difference between the experts, it was one of emphasis rather than substance.

Conclusion

83. The decisions in *Rescare* and *Bristol-Myers* are correct. The Full Court in the present case was correct to follow those decisions and conclude that the method claimed in the Patent was a patentable invention within s 18(1)(a) of the Act. The appeal should be dismissed with costs, and the appellant should be refused special leave to appeal in relation to the s 117 point.

Part VII: Argument on notice of contention

84. Not applicable.

Part VIII: Estimate of time

85. The respondents estimate that approximately 3 hours will be required for the presentation of their oral argument on the s 18(1)(a) issues, and 3.5 hours (in total) if the s 117 issue is permitted to be raised.

DATED: 15 February 2013

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[104] Appellant's submissions, para 74.
[105] [2012] FCAFC 102 at [154].