IN THE HIGH COURT OF AUSTRALIA
SYDNEY OFFICE OF THE REGISTRY Nos. S219 of 2012 & S1 of 2013

BETWEEN

APOTEX PTY LTD ACN 096 916 148
Applicant/Appellant

and

SANOFI-AVENTIS AUSTRALIA PTY LTD
First Respondent

SANOFI-AVENTIS DEUTSCHLAND GMBH
Second Respondent

AVENTISUB II INCORPORATED
Third Respondent

APPLICANT'S/APPELLANT'S REPLY

Part I: Suitable for publication

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

Part II: Reply

Methods of treatment

2. The Respondents (**Sanofi**) err in treating the ultimate finding in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (***NRDC***) as establishing "an exclusive [or] a conclusive test".[1] The reference to an "artificially created state of affairs" of "economic utility"[2] was the Court's answer to the Commissioner's contention that "manufacture" was "restricted to vendible products and processes for their production…"[3]

3. That the Court did not propound this as an exhaustive test is clear from the celebrated passage at 269, where the right question was said to be an inquiry into the breadth of the concept developed for the application of s6 of the *Statute of Monopolies 1623.*

4. The question whether an alleged invention comes within the definition might often be informed by asking whether it results in "an artificially created state of affairs", but this

[1] The phrase used by Aickin QC, for the patent applicant in *NRDC* at 255.
[2] Respondents' Submissions (**RS**) paragraph 20, referring to *NRDC* at 277.
[3] *NRDC* per Dixon CJ, Kitto and Windeyer JJ at 268. See also the submissions at 257-258.

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is not always sufficient, or "conclusive". See, for example, the business method cases where patentability does not follow from the mere use of a computer.[4]

5. Two *dicta* in *NRDC* concern methods of treatment. The first "put aside, as they apparently must be put aside, processes for treating diseases of the human body".[5] This was a "qualification" to a statement of Abbott CJ[6] which foreshadowed the Court's ultimate conclusion as to an "artificially created state of affairs".[7] Abbott CJ's statement could not be "conclusive of the question" because "the principles which have been developed for the application of s. 6 of the *Statute of Monopolies*" excluded methods of treatment from patentability.

6. The second *dictum* is in *NRDC* at 275. The Court again referred to the "exclusion of methods of surgery and other processes for treating the human body". The possibility that "the whole subject is conceived as essentially non-economic" was expressed in the context of the Court's reasoning towards the ultimate finding referred to above. In the same passage, the Court referred to "some advantage which is material... in the field of economic endeavour".

7. Sanofi's submission at **RS** paragraphs 17 and 30-33, that the exclusion of methods of treatment is not supported by decisions of this Court, cannot stand in the face of these *dicta*. The submission at **RS** paragraph 18 that such exclusions were "plainly never intended" is equally unsustainable, given that the same test for patentability applied then as now.

8. Barwick CJ's suggestion in *Joos v Commissioner of Patents* (***Joos***),[8] that any exclusion of methods of treatment had to be based on the "ground" of "generally inconvenient", was followed in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (***Anaesthetic Supplies***) and *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524 (***Bristol Myers-Squibb***).[9] His Honour had said this principally on the basis that *NRDC* undercut Dixon J's (as the Chief Justice then was) observations (or assumptions) in *Maeder v Busch* (1938) 59 CLR 684 (***Maeder v Busch***).[10] This suggestion involves an unlikely implication that the Court in *NRDC*, including Dixon CJ, had overlooked the forthcoming conclusion at 277 when citing *Maeder v Busch* at 270-271 and 275. The Applicant/Appellant (**Apotex**) submits that the better view is that, when the Court referred to the "whole subject" as "essentially non-economic", it meant something different from Barwick CJ's "national economic interest in... the repair and rehabilitation of members of the work force".[11] The Court's dictum relates to

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[4] *Research Affiliates LLC v Commissioner of Patents* [2013] FCA 71. The US Supreme Court recently rejected a "machine-or-transformation test" as the sole test for determining the patent eligibility of a process: *Bilski v Kappos*, currently at 130 S.Ct. 3218, 3225-3228 (2010); 561 US __, __ (2010).
[5] *NRDC* at 270-271.
[6] In *R v Wheeler* (1819) 2 B. & Ald. 345; 106 E.R. 392.
[7] *NRDC* at 277.
[8] (1972) 126 CLR 611. Cf **RS** paragraphs 34-37.
[9] **RS** paragraphs 36-37, 40-44.
[10] See **RS** paragraph 34; *Joos* at 617-618.
[11] Quoted in full at **AS** paragraph 28.

the true nature of an "invention". Treating a human to obtain a "better working organism"[12] has never been "a contribution to the productive arts".[13]

9. In *Maeder v Busch* at 705, quoting a lengthy passage from *Boulton v Bull*,[14] Dixon J interpolated: "[b]ut the ultimate end in view [of a patentable process] is the production or treatment of, or effect upon, some entity". It was in that sense that a method of treatment is "essentially non-economic". So to find is not a question of policy, as Sanofi asserts, but an application of "the right question": a human being is not an "entity", in the way that patent law has developed since 1623.

10. The "economic" factors of **RS** paragraphs 49-60 thus do not confront the sense in which the High Court said that "the whole subject is conceived as essentially non-economic". The policy argument in **RS** paragraph 58 also overlooks the fact that the patentee here had a 25 year monopoly (after extension) in the drug itself. The ways in which patentees can and do obtain patent monopolies for literally decades beyond the original 20 year term of a compound patent include, patents for new pharmaceutical formulations, new forms (e.g., polymorphs), new salts, new processes of manufacture of finished compounds and intermediates, and new mixtures with other drugs.

11. Sanofi's submission about "[t]he policy of the Act in providing an incentive for the stimulation of research"[15] is too simple. Since 1623, the law has permitted a limited exception to the prohibition on monopolies in the case of a "manner of new manufacture". The countervailing policies in favour of free competition, cheaper drugs and access to drugs are all articulated in the extrinsic materials with which the Court will be provided.

Post 1990 decisions

12. In each of *Anaesthetic Supplies* and *Bristol-Myers Squibb*, the claims were not novel. In both cases, the question of manner of manufacture turned principally on the question of "generally inconvenient" and on Barwick CJ's suggestion that the *NRDC* decision undercut the High Court's dicta.[16] "Inconvenience" is not the right basis for the exclusion of methods of treatment.

Long-standing practice

13. The "practice" referred to in **RS** paragraphs 18, 25 and 28 followed Barwick CJ's remarks in *Joos*. It was significant in the reasoning in *Anaesthetic Supplies* and *Bristol-Myers Squibb*.[17] The practice of the Commissioner is, however, of no present assistance, given its foundation in Barwick CJ's incorrect approach. Neither the Report of the Industrial Property Advisory Committee (**IPAC**),[18] nor any of the extrinsic

[12] *Re C & W's Application for a Patent* (1914) 31 RPC 235, cited in *Maeder v Busch* at 706.
[13] *Maeder v Busch* at 706.
[14] (1795) 2 BL.H 492; 126 E.R. 666.
[15] **RS** paragraph 58.
[16] See Lockhart J in *Anaesthetic Supplies* at 19; Wilcox J at 43-44.
[17] Per Lockhart J at 19; per Wilcox J at 44. See also at first instance *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 at 234 and 239. See also *Bristol-Myers Squibb* at 530.
[18] "Patents, Innovation and Competition in Australia" (29 August 1984) (**IPAC Report**).

materials relevant to the *Patents Act 1990* (Cth) (the **Act**) referred to the practice. IPAC recommended the retention of the present definition, noting that "[s]urgical and medical techniques for human therapy ... are regarded in many countries as unpatentable on public interest grounds".[19] The question remained one for the courts in the application of the statutory definition.

Post-Act "legislative history" and s18(2)

14. As the United States Supreme Court has observed, "[p]ost-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation".[20] This is not a case of ambiguity and "[a]n Act of Parliament does not alter the law by merely betraying an erroneous opinion of it".[21] See *Acts Interpretation Act 1901* (Cth), s15AB. It follows that Sanofi's reliance on post-1990 amendments (or non-amendments) to the Act is misconceived.

15. The legislature's omission to amend the law to overcome the *dicta* in *Anaesthetic Supplies* and *Bristol-Myers Squibb* also does not assist.[22] Section 119A was added in 2006 and Sanofi omits[23] the only specified "method... relating to a pharmaceutical substance", namely "a method for producing a raw material needed to produce the substance". That does not advance the question of methods of treatment. The very specific legislative history of s18(2)[24] does not support an *expressio unius* argument by the inclusion of a single specific exception.

Second medical use

16. Contrary to **RS** paragraph 68, Apotex made it clear that its argument was that, if methods of treatment were patentable, which it denied, they were only patentable if limited by purpose. Apotex's repeated submission as to the ensuing difficulties with claims limited by purpose is recorded, for example, by Jagot J at [139].[25] The Full Court rejected Sanofi's construction, adopted by Jagot J, that the claim was infringed if the "effect in fact" was to treat psoriasis. The Court held that the claim did involve an element of purpose. On that holding, the second medical use question squarely arises and special leave was granted to consider it.

17. A "second medical use" occurs when a compound is initially patented as such, being useful for a "first medical use". A second therapeutic use is later discovered, as in this case. Apotex cannot understand Sanofi's submissions that the specification does not

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[19] IPAC Report at 40.
[20] *Bruesewitz v Wyeth LLC*, currently at 131 S.Ct. 1068, 1081 (2011); 562 US __, __ (2011).
[21] *Deputy Federal Commissioner of Taxes (South Australia) v Elder's Trustee and Executor Company Limited* (1936) 57 CLR 610 at 625 citing Maxwell, *Interpretation of Statutes* (6th ed, 1920) 544.
[22] See, e.g., **RS** paragraph 46.
[23] Section 119A is referred to in **RS** paragraph 27.
[24] In short, this related to Senator Harradine's concern about the possibility of patenting new forms of animal life and cloning. Cf **RS** paragraphs 26 and 46.
[25] *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* (2011) 196 FCR 1 (***Sanofi v Apotex (No 3)***).

disclose this.[26] See p1 lines 6-14 of Australian Patent No 670,491[27] (Leflunomide is compound 1), and claims 1 and 4 of Australian Patent No. 529,341.[28]

18. The asserted new purpose is the only possible basis for a new patent for the old compound. As submitted in chief, this gives rise to insuperable difficulties. Purpose-based claims for a second medical use are not claims for a manner of manufacture.

Overseas jurisdictions

19. Contrary to **RS** paragraph 74, the exclusion in the UK was not merely "based on policy grounds". It reflected the existing position in UK and European law. The Patents Act 1977 (UK) (the **1977 UK Act**) and the European Patent Convention continued the existing exclusions of methods of treatment that the law had developed. This was done, at first, by a statutory deeming that they were not capable of industrial application. It is the "devices"[29] used since then (Swiss-form claims and, e.g., s4A of the 1977 UK Act) that allow the patenting of a product as being novel if it is "for" a new purpose. That approach is untenable in Australia for the reasons suggested by Lord Hoffman in *Merrell Dow.*[30] The reluctant acquiescence of the UK courts in accepting these devices has been evident. In particular, the European approach requires such claims to be read as possessing an implied integer, "the technical result".[31] This is the very "effect in fact" construction rejected by the Full Court. In Australian patent law, purpose cannot be an element of direct patent infringement. The continued reliance on the device of Swiss-form claims in New Zealand and Canada suggests similar difficulties in principle.

s117

20. Special leave should be granted to consider the "reason to believe" required by s117(2)(b), in the context of an important statutory milieu in which "indications" are strictly regulated. Apotex was found liable under s117(2)(b) on two incorrect bases: the "effect in fact" construction (rejected by the Full Court) and the preference for Professor Brooks's "expectation" about psoriasis over Professor Smith's focus on rheumatic disease. Apotex accepts that it must also overcome the double negative construction that was an alternative basis ("if the point is not moot")[32] of Jagot J's finding under s117(2)(c), but this is a very short point. Her Honour's principal basis was the wrong "effect in fact" construction.

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[26] **RS** paragraphs 70-71.
[27] Application/Appeal Book (**AB**), Volume 1, p414.
[28] **AB**, Volume 1, p218-219. Her Honour Justice Jagot found that claim 4 related to rheumatoid arthritis.
[29] **RS** paragraphs 75-76.
[30] *Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd* [1996] RPC 76 (***Merrell Dow***) at 92.
[31] *Merrell Dow* at 92.
[32] Per Jagot J in *Sanofi v Apotex (No 3)* at [262].