IN THE HIGH COURT OF AUSTRALIA **No. S28 of 2015**
SYDNEY REGISTRY

BETWEEN: **YVONNE D'ARCY**
Appellant

AND: **MYRIAD GENETICS INC**
and
GENETIC TECHNOLOGIES LIMITED
Respondents

APPELLANT'S REPLY

Part I: Publication

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

Part II: Reply

2. The Chief Justice set out the legislative history of s18(1)(a) in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 304 ALR 1; [2013] HCA 50 at [8]-[16], concluding at [16] that "*the legislative purpose reflected in s18(1)(a) of the 1990 Act is that the 'manner of manufacture' criterion for a patentable invention ought to continue to be applied on a case-by-case basis.*"

3. His Honour noted that a "more inflexible codified definition" was rejected in 1990, at [16]. The fate of exceptions propounded in 1990, or since, is irrelevant. Cf **RS** paras 68-72. To adopt the Chief Justice's remarks at [49], "*the resolution of this important question cannot rest upon the shifting sands of legislative silence. The argument has to engage with the case-by-case development of principle, which the legislature has left to the courts ...*". See also at [19].

Molecule, "encode" and "coding for"

4. To say that a product is a molecule, or a chemical compound, or a sequence of nucleotides made up of chemical components (cf **RS** paras 4, 30-31), does not advance the present question: its resolution depends on the nature and

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significance of any differences that exist between the claimed nucleic acids and their counterpart in nature. The first Respondent seems now to go so far as to rely on the breaking of hydrogen bonds. See, e.g., **RS** paras 12 and 48.

5. The claims use "coding for" in the sense of possessing the code (for a mutated polypeptide). The Full Court's distinction, embraced at **RS** para 36, between "code for" – "passive" and "encode" – "actually to produce the polypeptide", entirely misreads the claim. The utility of the nucleic acid of claim 1 is not that it produces the protein that causes a predisposition to cancer. The "function" that is relevant is the possession of the genetic code – this shows whether a person's DNA has one of the mutations or polymorphisms in the tables.

6. It does not matter whether cDNA is a manner of manufacture, cf **RS** paras 42-43. DNA sequences that have been isolated from a living person's blood can fall within the claims. It is common ground that, if these sequences are not patentable, the claims in suit are invalid. As **RS** para 46 notes, SEQ.ID No: 1 is "the cDNA which does not exist in nature" – it is, however, the coding sequence of the gene. As **RS** para 23 says, the Patent relates to the identification of "the BRCA1 gene, its nucleic acid sequence and the characteristics and sites of mutations". All of these relate to the natural coding sequence.

7. The evidence at T96.28-97.9, which is the basis of the first Respondent's "chemical bonds" thesis, shows that a shorter length of DNA that has been randomly isolated by known processes, will have a broken covalent bond at its beginning and end. See **RS** para 48. The claim asks whether, within that extract of DNA, there is a sequence of at least 15 nucleotides of the BRCA1 gene that possesses one of the specified mutations or polymorphisms.

Administrative practice

8. There is no evidence of any practice of granting patents whose only claims are to isolated genes or other biological materials. As with the present Patent, the patents that have actually been granted presumably relate principally to applications of the isolated gene, such as methods of diagnosis or treatment. See **RS** paras 90-91 and Article 5.3(3) of the EC directive.

9. In addition to the matters referred to at **RS** para 70, the ALRC report said in para 6.57 that its terms of reference did not extend to "general reform of the way in which Australian patent law should approach the concept of patentable subject matter". The ALRC was equivocal on the present issue, referring to "legitimate concerns" but saying that the time had passed for taking a different approach, given the Commissioner's practice, at paras 6.51-6.52.

10. The Commissioner's practice has been, relevantly, that she *"ought not to refuse acceptance of an application unless it is practically certain that letters patent granted on the specification would be held invalid"*: *Commissioner of Patents v Microcell Limited* (1959) 102 CLR 232, at 244-245; s49 of the Act. See *Corporation of the City of Enfield v Development Assessment Commission* (2000) 199 CLR 135; [2000] HCA 5, [39]-[48]. The US Supreme Court put aside the practice of the US Patents and Trade Mark Office in *Myriad* at 2118.

11. This case is thus different from *Apotex v Sanofi*. Patents for methods of medical treatment had been granted since Barwick CJ's decision in *Joos v Commissioner of Patents* (1972) 126 CLR 611. See at 615. See per Crennan and Kiefel JJ at [284]. There is no question here of a judicially sanctioned orthodoxy, such as was referred to by Gageler J in *Apotex v Sanofi* at [315].

12. Claims 1-3 do not claim the practical application of the patentee's discovery. Cf **RS** para 51. By contrast, claims 17-30 apply the discovery to genetic testing; claim 4 applies it to a probe (**AB**(2) 568-572). There are no claims to gene therapy; the description at **AB**(2) 427-430 refers to the use of the normal gene. Apart from the Patent, only Professor Brown's patent was in evidence, **Ex 2**. This claimed methods of treatment using fragments of genes, rather than an isolated gene, *per se*. The distinction between a discovery and its application is drawn in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, at 263-4 and *Association for Molecular Pathology v Myriad Genetics Inc* 133 S. Ct 2107 at 2120.

Products of nature

13. The Appellant's case is not that an invention is not patentable where there "is a single attribute in common between that which is claimed and that which occurs

in nature", cf **RS** para 77. To the contrary, the Appellant's proposition is that where, as a matter of substance, a claim is merely to a naturally occurring thing, then, even if it is "isolated", it is not a claim to a manner of manufacture. Despite isolation, in substance it is the same. This was the approach of the US Supreme Court in *Myriad* at 2116-2118.

14. The question of substance was expressed in *Diamond v Chakrabarty* 447 US 303 (1980) as that the bacterium was "markedly different" from nature, at 309-310. In *Mayo Collaborative Services v Prometheus Laboratories Inc* 132 S. Ct. 1289 (2013) the claims extended "just minimally beyond a law of nature", at 1303. See, in a different context, *Research Affiliates LLC v Commissioner of Patents* (2014) 109 IPR 364; [2014] FCAFC 150, at [45]-[58]; esp. at [106].

15. By contrast, the first Respondent's case is that a chemical difference as trivial as a broken bond confers sufficient artificiality. As the Supreme Court said in *Myriad*, the claims are simply not expressed in terms of chemical composition.

16. **RS** paras 79-84 misunderstand the structure of the reasons in *NRDC*. At (1959) 102 CLR 252, 261-262, the Court distinguished two concepts: whether the invention claimed is "within the concept of a 'manufacture'" and, as in *Microcell*, whether on the face of the specification, the invention claimed "is new". Frankfurter J's dictum in *Funk Brothers Seed Co v Kalo Innoculant Co* 333 US 127 (1948) at 134-135 appears in the latter context, at 263-264. Cf **RS** para 81. The Supreme Court's reasoning as to phenomena of nature (per Douglas J) in *Funk* at 130-132 has prevailed: see *Myriad* at 2116-2117.

17. The High Court discussed the "concept of manufacture" in *NRDC* from 268-279, in terms of an "artificially created state of affairs". Compare fruit and other growing crops, where *"however advantageously man may alter the conditions of growth, the fruit is still not produced by his action"*, at 278. The question here is whether isolation of the gene is sufficient non-natural "action" by man.

18. 35 USC § 101 has historical and verbal affinity with s6 of the Statute of Monopolies. See *Graham v John Deere Co* 338 US 1 (1966), 5-12. The law of patentable subject matter has developed in the same way as described in *NRDC*.

Intervention by the Institute of Patent and Trade Mark Attorneys

19. The Appellant opposes IPTA's application to intervene.

20. No constitutional question has been raised by the parties. The question whether a manner of manufacture is claimed does not involve "the full permissible landscape" of the constitutional power: cf IPTA Submission paras 32-34.

21. No question concerning the patentability of "other materials isolated from nature" arises on the facts of the present case. The patentability of the isolated DNA of the claims in suit is fully addressed by the parties.

22. Assertions as to the impact on research and innovation if the present claims are held not to be patentable are expressed tendentiously and in inadmissible form by IPTA's deponents. When able to be tested, they are questionable. For example, among many references to patents for natural materials, only one patent is exhibited, **Ex SMK-3** to the affidavit of Sherry M Knowles. This is for a bacterium that was "obtained by mutageneous treatment" of a naturally occurring bacterium. See **AB**(2) 846, col 1 lines 45-50. This is analogous to *Chakrabarty*, not the present case. Cf IPTA Submission paras 35-36.

23. *Amici,* including the United States, made submissions in *Myriad,* contrary in effect to those of the IPTA, about the impact of gene patents on research and innovation. Hayne J's remarks in *Apotex v Sanofi* at [76] are apposite: economic and political issues such as those raised by IPTA are not susceptible to resolution in the present adversarial proceeding, *a fortiori*, when they are not in evidence in the matter. See also *Mayo v Prometheus* at 1304-1305.

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