澳洲聯邦最高法院D′Arcy v Myriad Genetics Inc判決摘譯

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D′Arcy v Myriad Genetics Inc

High Court of Australia
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譯註： D'Arcy v. Myriad Genetics, Inc. 為澳洲聯邦最高法院（High Court of Australia）針對 Myriad 公司所擁有 686004 號專利請求項 1 至 3 是否有效所作之判決。系爭發明係關於編碼 BRCA1 及 BRCA2 多肽之分離基因組 DNA，其 DNA 序列與指示乳癌及卵巢癌發生可能性有關。本案爭點為系爭發明是否符合澳洲 1990 年專利法（Patents Act 1990）第 18(1) 條所規定具可專利性的要件，是否符合壟斷法（Statute of Monopolies）第 6 條「生產方式（manner of manufacture）」之概念。本案澳洲法院初審（the primary judge）及上訴審（the Full Court）皆認為系爭發明具可專利性。不同於美國聯邦最高法院（Supreme Court of the United States）Association for Molecular Pathology v. Myriad Genetics, Inc. 案認為人類基因序列不具可專利性，然從 mRNA 作成只含有外顯子的 cDNA，不是自然存在的，因此具可專利性。本案澳洲聯邦最高法院（High Court of Australia）多數意見，基於基因序列應理解為「訊息（information）」、考量對相關研究與發展產生寒蟬效應等理由，認為從基因組中取出並從細胞中分離之基因序列，包含 cDNA，皆不具可專利性。

(i)　The statutory framework

(i)　法條結構

p.6 /paragraph11

Section 18(1) sets out "the essential characteristics of a 'patentable invention' for the purposes of the Act." Section 18(1)(a) provides:
第 18(1) 條闡述了「符合本法目的而『具可專利性之發明』的重要特徵。」第 18(1)(a) 條規定：

"Subject to subsection (2), a patentable invention is an invention that, so far as claimed in any claim:
「具可專利性之發明係指，以第 (2) 款為前提，任何請求所主張的發明：

(a)is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies".
(a) 為壟斷法（the Statute of Monopolies）第 6 條所定義的生產方式。」

The other requirements of s 18(1) of novelty, inventive step, usefulness and no secret user before the priority date are not raised in this appeal. Nor is s 18(2), which precludes the patentability of "[h]uman beings, and the biological processes for their generation".
其他依第 18(1) 條所須符合的要件，新穎性、進步性、產業可利用性以及在優先權日前無可主張秘密先前技術之權利人，並未在本上訴提出。第 18(2) 條，即排除「人類及其繁殖的生物過程不具可專利性」之規定，亦未在本上訴提出。

p.7/ paragraph12

The term "patentable invention" is defined in the Dictionary in Sched 1 to the Act as "an invention of the kind mentioned in section 18." The term "invention" is defined as :
「具可專利性之發明」在本法附表 1 字彙表中定義為「第 18 條所提及之發明。」「發明」之定義為：

"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."
「符合壟斷法第 6 條，任何為取得專利證書和特權授予的新生產方式，並包含一項聲稱的發明。」

It is not clear, and was not debated in this appeal, how the expression "manner of manufacture" differs from the expression "manner of new manufacture". The definition of "invention" has been used in Commonwealth patent statutes since federation. It allows for exclusion from the class of "invention", and therefore from the class of "patentable invention", anything which

is not, on the face of the specification, a proper subject of letters patent according to traditional principles. That anterior exclusion may be based upon an admission, on the face of the specification, which makes clear that the invention claimed is not novel or does not involve an inventive step. This appeal, however, collapses the anterior and subsequent questions — "Is there an invention?" and "Is there a patentable invention?" — into one inquiry. That inquiry requires a definition of the allegedly patentable invention. That definition depends upon the construction of the impugned claims read in the light of the specification as a whole and the relevant prior art. The prior art in this case was reflected in expert evidence at trial and set out in the scientific primer agreed between the parties and summarised later in these reasons.

對於「生產方式」和「新的生產方式」並無清楚區分，在本上訴中亦未爭論。自組成（澳大利亞）聯邦以來 Commonwealth patent statutes 就已將「發明」作如前的定義。該定義可排除專利說明書乍看下所呈現的、廣義的「發明」，因此亦排除廣義的「具可專利性的發明」—依長期以來的原則，這些被排除的「發明」並非專利證書所欲保護之對象。發明被前開定義所排除之情況，亦可能是由「自認（admission）」所造成，即依其專利說明書呈現，其主張保護的發明顯不具備新穎性或進步性。然而，本上訴將前開問題「是發明嗎？」和後一問題「是具可專利性的發明嗎？」合併成一個問題。回答這個問題須對聲稱具可專利性之發明進行定義。這個定義係基於對系爭請求項的理解，而須考量專利說明書之整體以及相關的先前技術。本案的先前技術呈現於一審時的專家證言證據，其淺顯的科學說明亦經雙方當事人同意，將摘要於後段論理部分。

p.8/ paragraph13

The conditions of patentability in s 18(1) must be satisfied by the invention "so far as claimed in any claim". That term directs attention to the formal requirement of s 40(2)(b) that a complete application for a standard patent must "end with a claim or claims defining the invention". The word "invention" in that context does not import the definition in the Dictionary, but means "the embodiment which is described, and around which the claims are drawn".

「任何請求所主張的發明」，必須符合第 18(1) 條所規定具可專利性的要件。這個要件也須注意第 40(2)(b) 條所列的形式要求，即完整的專利申請必須以「在一個請求項或多個請求項中界定其發明」作結。此處的「發明」並不援用本法字彙表中的定義，而係指「所描述之實施例以及請求項所劃定的約略範圍」。

p.8/ paragraph14

Historically, the claim, as definer of the inventor's property, emerged in the late 19th century. The statutory requirement to set out at the end of a complete specification a "distinct statement of the invention claimed" first appeared in s 5(5) of the Patents, Designs, and Trade Marks Act 1883 (UK). It was reflected in successive Commonwealth patent statutes from the time of federation. The function of the claim was described by Lord Russell of Killowen in 1938 as "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." Its limiting role was emphasised:
從歷史上來看，於 19 世紀末，請求項被用於界定發明者之財產。在專利說明書的最後須「清楚界定所要求保護的發明」之法規要求首次出現在 the Patents, Designs, and Trade Marks Act 1883 (UK) 第 5（5）條。自組成聯邦以來 Commonwealth patent statutes 中也有要求。請求項的功能在 1938 年 Killowen 勳爵 Russell 描述為「明確界定所要求保護壟斷權的準確性，使他人能預見確切的權利侵害範圍。」請求項的限制作用受到重視。

"It and it alone [defines] the monopoly; and the patentee is under a statutory obligation to state in the claims clearly and distinctly what is the invention which he desires to protect."
「請求項本身就界定了壟斷權；在法規的要求下，專利權人有義務在請求項中清楚且明確地描述其所要求保護的發明是什麼。」

Lord Russell's observations have stood the test of time in the United Kingdom as "[t]he best-known statement of the status of the claims in UK law". They also describe the function of the claim mandated by s 40(2)(b) of the Act. As succinctly, but accurately, stated in a recent Australian text that function is "to define what it is that the patentee has exclusive right to, during the term of the patent." The breadth of the class of invention claimed in this case, using the generic term "isolated nucleic acid", makes definition of the boundaries of the monopoly which is sought elusive.
Russell 勳爵的見解通過了時間的考驗，是英國法中最著名的、對請求項功能的說明。其見解還描述了本法第 40(2)(b) 條所要求之請求項的功能。近期澳洲法的教科書簡要地援引了其見解，認為請求項之功能是「明確界定專利權人於專利權保護期間所擁有排他權之內容」。本案中，所要求保護的發明類別是「分離的核酸」這樣空泛的名詞，使得壟斷權的界線難以明確界定。

p.9/ paragraph15

The rights of the patentee are conferred by s 13(1) of the Act, which provides:
專利權人的權利由本法第 13(1) 條賦予，其規定：

"Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention."
「以本法為前提，在專利保護期間，專利權給予專利權人可以實施其發明和授權他人實施其發明的排他權。」

The term "exploit" in relation to an invention includes:
「實施」發明的意思包含：

"(a)where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
「(a) 物之發明之實施，包含製造、租借、販賣或其他對物之處置，為製造、販賣、租借或其它對物處置之要約，物之使用或進口，或其它為上述之目的而為之任何行為；或

(b)where the invention is a method or process—use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use."
(b) 方法發明之實施，包含使用該方法或製程，或對使用該方法或製程所產生之物為任何前述 (a) 段所述之行為。」

p.10/ paragraph16

The definition of "exploit" distinguishes between an invention which is a product and an invention which is a method or process which may or may not yield a product. In Northern Territory v Collins, Gummow ACJ and Kirby J linked that distinction to the way in which, over time, the expression "manner of manufacture" had been construed to include the practice and means of "making", as well as its product, which would include an economically useful outcome effected by an inventive method. The idea of something which can be "made" by human intervention is central and long standing — "'[m]anufacture' connotes ... the making of something." It is an important element of the exclusive right to exploit a patented product.
「實施」的定義區分為物之發明，及不論是否製造出物的、方法或製程之發明。在 Northern Territory v. Collins 一案中，Gummow 代理首席法官 (ACJ) 和 Kirby 法官將前述「實施」該區分連結「生產方式」之定義，隨著時間而逐漸將「生產方式」解釋為包含「製造」的方法和實行，以及依照該生產方式所產生具有經濟利用價值之物，而該物具有經濟利用價值是因為該發明方法所產生的結果。某物能藉由人為方式製造出來的想法是長期存在的核心概念－「生產意味著製造某個東西。」這是利用受專利保護之物的排他權的重要內涵。

p.10/ paragraph17

The proceedings for the revocation of the Myriad patent Claims 1 to 3, which have led to this appeal, were instituted under s 138 of the Act. The relevant ground for revocation is that set out in s 138(3)(b):
本上訴，撤銷被告 Myriad 專利請求項 1 至 3，是根據本法第 138 條。有關撤銷的理由是在第 138(3)(b) 條：

"that the invention is not a patentable invention".
「該發明是不具可專利性的發明」。

The answer to the question of patentability raised by that ground depends upon the principles governing the criterion prescribed by s 18(1)(a), considered in the next section of these reasons.
依前述所提出對具可專利性的挑戰，須依第 18(1)(a) 條揭示之原則及衍生的具體標準判斷，會於判決理由的下一節考量。

(ii)A manner of manufacture — relevant principles.

(ii) 生產方式－相關原則

p.11/ paragraph18

The legislative history of the requirement for patentability imposed by s 18(1)(a) of the Act has been set out in previous decisions of this Court. The question posed by the application of s 18(1)(a) may be framed as in NRDC :
關於本法第 18(1)(a) 條所規定具可專利性之要件的修法歷程已在本法院以前的裁判中闡述。第 18(1)(a) 條適用上的問題可能和 NRDC（National Research Development Corporation v. Commissioner of Patents）一案有關：

"Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?"
「根據適用壟斷法第 6 條所建立的原則來核發專利證書是否適當？」

That question is to be answered according to a common law methodology under the rubric of "manner of manufacture" as developed through the cases, but consistently with "a widening conception of the notion [which] has been a characteristic of the growth of patent law." That widening conception is a necessary feature of the development of patent law in the 20th and 21st centuries as scientific discoveries inspire new technologies which may fall on or outside the boundaries of patentability set by the case law which predated their emergence.
這個問題要依照普通法的方法來回答，「生產方式」的標準透過幾個判決發展，不斷擴張其概念，這可以說是專利法成長的象徵。因為科學發現激發新的技術產生，使概念的擴張成為 20、21 世紀專利法發展的必然結果，而在新技術出現前已由判例法界定「具可專利性」之範圍即可能恰好涵蓋了這些新技術，也可能無法包含之。

p.11/ paragraph19

The Court in NRDC upheld the validity of a patent for the use of previously unknown properties of a known chemical to effect a new purpose. The Court generalised what had come to be treated, erroneously, as a "rule", that for a method or process to be a "manner of manufacture" it

should result in the production, improvement, restoration or preservation of a "vendible product". By treating the word "product" as covering every end produced and the word "vendible" as pointing to the requirement of utility in practical affairs, the vendible product "rule" could be accepted as wide enough to convey the broad idea which a long line of authority on the subject had been shown to be comprehended by the Statute . The Court said of the method patent in suit before it:
法院於 NRDC 一案中判定一項運用已知化學品的未知特性來達成新效果之專利有效。該法院錯誤地將「生產方式」的「標準」，歸納為用以製作、改進、恢復或保存一個「可販賣產品」的方法或製程。通過把「產品」一詞視為涵蓋所有最後生產的成果，以及將「可販賣的」一詞指向需要在事物上實際可應用，可販賣產品「標準」被接受，是因為這個標準適用範圍廣，足夠傳達專利的廣泛概念，而這標準被一系列相關判決採納、切合法條所表達的意義。該法院針對該訴訟的方法專利表示：

"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 ..."
「上訴人的方法所產生的成果表現出『產品』和『可販賣的』兩個必要要件。這是一個『產品』，因為它處於人為創造的狀態，透過一段時間的觀察，可以發現雜草和作物分別在播種的土地上生長，這是上訴人方法的實際應用。而且產品是具備經濟意義 ...」

p.12/ paragraph20

The terminology of an "artificially created state of affairs of economic significance" is to be understood in the context in which it was used in NRDC. It was not intended as a formula exhaustive of the concept of manner of manufacture. The Court made that point emphatically:
「人為創造具有經濟意義的狀態」的意思應該在 NRDC 使用的背景中理解。法院無意使其作為生產方式概念的完備公式。該法院強調了這一點：

"To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound."
「試圖以一個精準的語言公式束縛生產方式的概念是不可能完備的。」

Hayne J made it in Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd :
Hayne 法官在 Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd 一案中表示：

"Nothing said in the Court's reasons for decision in that case can be taken as an exact verbal

formula which alone captures the breadth of the ideas to which effect must be given."
「法院在該案提出的判決理由不能被當作一個精準的語言公式。」

In similar vein, Crennan and Kiefel JJ, with whom Gageler J agreed, said that:
同樣的，Crennanz 法官和 Kiefel 法官同意 Gageler 法官說道：

"In Australian law, the starting point is the recognition in the NRDC Case that any attempt to define the word 'manufacture' or the expression 'manner of manufacture', as they occur in s 6 of the Statute of Monopolies, is bound to fail."
「在澳洲法律中，從 NRDC 一案以來認識到，任何試圖定義壟斷法第 6 條所述『生產』或『生產方式』的意思，一定會失敗。」

It is true that in Anaesthetic Supplies Pty Ltd v Rescare Ltd Lockhart J in the Full Federal Court, in a passage endorsed by Crennan and Kiefel JJ in Apotex , said:
確實，在判決 Apotex 中，Crennan 和 Kiefel 法官同意 Lockhart 法官其在 Anaesthetic Supplies Pty Ltd v Rescare Ltd 一案上訴審 (the Full Federal Court) 中所述，Lockhart 法官說：

"If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture' within s 6 of the Statute of Monopolies."
「如果一個方法不能產出新的物質，但能產生『新的又有用的結果』，這個新的結果就是具有經濟效益的『一個人為創造的狀態』，就可能符合壟斷法第 6 條中的『新的生產方式』。」

Importantly, however, his Honour used the word "may". Neither Lockhart J nor Crennan and Kiefel JJ should be read as holding that satisfaction of that formula would mandate a finding of inherent patentability. That is not to say that it will not suffice for a large class of cases in which there are no countervailing considerations.
但重要的是，Lockhart 法官使用的詞是『可能』。上述 Lockhart 法官和 Crennan 以及 Kiefel 法官的意見都不必然足以判斷具可專利性。但是，若無相反的考量，前開標準難謂不足用於判斷絕大多數的案件。

p.13/ paragraph21

In CCOM Pty Ltd v Jiejing Pty Ltd, the Full Court of the Federal Court said the NRDC case "requires a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the field of economic endeavour." As Professor Monotti wrote in an article in the Federal Law Review in 2006, the passage from the judgment in NRDC characterising the pro-

cess claimed before the Court as a product consisting in an "artificially created state of affairs" merely explained "the qualities of the invention before the court." The Court could hardly have intended the phrase to be seen as a definition of manner of manufacture because it had already denounced the idea of an exact formula. The formulation in CCOM, like the so-called vendible product "rule", should be taken as a guide rather than as a rigid formula.
在 CCOM Pty Ltd v Jiejing Pty Ltd 一案中，上訴審表示，NRDC 中「要求方法必須達成一個最終結果，該結果是一個可供該領域經濟利用的人為創造狀態」。正如 Monotti 教授在其 2006 年文章 Federal Law Review 中寫道，NRDC 判決中描述系爭方法是一個「人為創造狀態」的結果，只是拿來說明系爭標的具備發明的性質。該法院不可能將其所述視為生產方式的定義，因為該法院已經抨擊了一個精準公式的想法。在案子 CCOM 判斷標準，所謂的可銷售產品「標準」也是一樣，應視為一個指引，而非一個剛性的公式。

p.14/ paragraph22

Counsel for Myriad posited "the test" in NRDC for patentability of a product as — "is it an artificially created state of affairs of economic utility?". Myriad's approach was accepted by the primary judge who derived from NRDC the proposition that:
Myriad 的辯護人主張，判斷產品是否具可專利性的判斷標準即為 NRDC 中的「是否人為創造具有經濟效用的狀態？」。本案的初審法官（primary judge）接受 Myriad 援用 NRDC 的方式，也植基於 NRDC 的立場，認為：

"a product that consists of an artificially created state of affairs which has economic significance will constitute a 'manner of manufacture'."
「一個產品若是人為創造的狀態且具有經濟意義就會構成『生產方式』。」

In similar vein, the Full Court said of NRDC that:
同樣地，本案上訴審論及 NRDC 表示：

"The Court held that it is sufficient for a product to result in 'an artificially created state of affairs', leading to 'an economically useful result'."
「NRDC 法院認為一個產品的結果為『一個人為創造的狀態』並導致『 經濟上有用的結果』即為已足。」

That proposition underpinned the conclusion by the Full Court in the second last paragraph of its judgment that:
前述主張支持本案上訴審做出的結論，在其判決倒數第二段表示：

"The isolated nucleic acid, including cDNA, has resulted in an artificially created state of affairs

for economic benefit. The claimed product is properly the subject of letters patent. The claim is to an invention within the meaning of s 18(1) of the Act."
「分離的核酸，包含 cDNA，是一個人為創造的狀態且具有經濟利益的結果。主張保護的產品可以核發專利證書。該請求項為本法第 18(1) 條所指的發明。」

Myriad' s proposition and the approach of the primary judge and the Full Court, with respect, rested upon an unduly narrow characterisation of the effect of the decision in NRDC. It rested upon the premise that the claims were for a product well within existing conceptions of a "manner of manufacture".
Myriad 的主張以及初審法官和上訴審的分析方式，過度狹隘解釋 NRDC 判決的效力。他們的主張是以產品請求項符合現行「生產方式」的概念為前提。

p.15/ paragraph23

This Court in NRDC did not prescribe a well-defined pathway for the development of the concept of "manner of manufacture" in its application to unimagined technologies with unimagined characteristics and implications. Rather, it authorised a case-by-case methodology. Consistently with that approach, and without resort to the "generally inconvenient" proviso in s 6 of the Statute of Monopolies, there may be cases in which the court will decide that the implications of patentability of a new class of invention are such that the invention as claimed should not be treated as patentable by judicial decision.

NRDC 的法院就其如何將「生產方式」的概念適用於未曾預見的科技（具備未曾預見之特色及應用方式），並未規定一個明確的途徑。相反地，它採取逐案認定的方式。在一些案子中，法院採逐案認定的做法，且未訴諸於壟斷法第 6 條附加限制條款「普遍不便性（generally inconvenient）」，法院會決定給予新類別的發明具可專利性的影響，因此判決主張保護的發明不應具可專利性。

p.15/ paragraph24

The Full Court disclaimed any consideration of "whether, for policy or moral or social reasons, patents for gene sequences should be excluded from patentability." The question for its determination, however, was not whether a claimed invention, prima facie patentable, should be denied patentability by judicial fiat. The question was whether the claimed invention lay within the established concept of a manner of manufacture and, if not, whether it should nevertheless be included in the class of patentable inventions as defined in s 18(1)(a) of the Act. Purposive and consequentialist considerations which, no doubt, could be classed as "policy" reasons may play a part in answering the second limb of that question. As Professor Monotti percipiently remarked in her article in the Federal Law Review, which, of course, predated Apotex:

上訴審拒絕任何考量「是否由於政策、道德或社會的原因，應將基因序列專利排除在具可專利性之外」。然而，對初步印象具可專利性之發明，問題不在該發明是否應由法院以命令（fiat）判斷其不具可專利性。要討論的問題是主張保護的發明是否屬於「生產方式」的概念之內，若否，則是否屬於在本法第 18(1)(a) 條所定義的具可專利性之發明類別中。毫無疑問地，目的與結果解釋是「政策」考量，或可用於分析第二個問題。正如 Monotti 教授在 Federal Law Review、早於 Apotex 一案的文章中所洞察的：

"Although it was important to expand patentable subject matter and remove artificial fetters on patentable subject matter at the time of NRDC, there is no consensus that we should continue to expand the scope of patentable subject matter into all fields of endeavour so as to remove the remaining fetters on patentable subject matter. The continuing debates on whether methods of medical treatment, business systems and genes should be patentable subject matter demonstrate that there is no universal acceptance of an approach that would accept that anything under the sun invented by man is patentable."
「雖然在 NRDC 時期，擴大具可專利性的內容，以及移除人為對具可專利性內容的束縛非常重要，但對於是否應持續將具可專利性內容的範圍擴大到所有領域，以便移除剩下對具可專利性內容的束縛，我們尚無共識。對於醫學治療、商業模式和基因的方法是否應具可專利性不斷地有所爭論，顯示出在太陽底下，人類所發明的任何東西皆具可專利性，這個主張並未普遍接受。」

The proposition that patents should extend to "anything under the sun that is made by man" was a statement of legislative intention attributed to Congress by the Supreme Court of the United States in Diamond v Chakrabarty in relation to 35 USC §101 which provides:
專利應擴展到「太陽底下，人類所製造的任何東西」這個主張，是美國聯邦最高法院在 Diamond v Chakrabarty 案例中對於立法目的說明，其有關於 35 USC §101：

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."
「以符合本法要件和條件為前提，任何新且有用的程序、機器、製造物或組合物的發明或發現，或任何前述項目新且有用的改良，可因此獲得專利。」

p.16/ paragraph25

NRDC was decided in 1959. The Act in 1990 re-enacted, in s 18(1)(a), the definition of "invention" in the Patents Act 1952 (Cth), to which NRDC was directed. That re-enactment bore with it the judicial methodology for its application and the constraints attaching to that methodology. The proper function of the judicial branch was considered in an analogous, but not identical, context in two successive decisions of the Supreme Court of the United States in 1978 and 1980. In

Parker v Flook , the Court said that the judiciary "must proceed cautiously when ... asked to extend patent rights into areas wholly unforeseen by Congress." In Chakrabarty, Burger CJ, writing for the majority, and finding for patentability of a manufactured micro-organism as "any new and useful ... manufacture, or composition of matter" under 35 USC §101, said:
NRDC 於 1959 年作成。NRDC 所依據者為 1952 年專利法，而該法 18(1)(a) 條關於「發明」之定義於 1990 年重新修訂。新修法援用美國最高法院所採用的分析方式及其界限。司法部門的適當職能在美國最高法院於 1978 年和 1980 年相繼做成的兩個判決中，亦有雖非相同、但相似的討論。在 Parker v Flook 一案中，該法院認為司法部門「當被要求將專利權擴大到國會完全無法預見的區域時，必須小心謹慎。」在 Chakrabarty 一案中，Burger 首席大法官所主筆的多數意見根據 35 USC §101，判定人為生產製造的微生物為「任何新且有用的 ... 製造物或組合物」具可專利性，表示：

"It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is 'the province and duty of the judicial department to say what the law is.'"
「理所當然的，國會，而非法院，必須界定具可專利性的界線；但同樣地，一旦國會完成立法，司法部門就有義務說明法律是什麼。」

The majority rejected the proposition that the claim before them was a matter of high policy for resolution within the legislative process, saying that the contentions to that effect should be pressed on the political branches of government and not on the courts. Brennan J, who was joined in dissent by White, Marshall and Powell JJ, put the other side of the argument:
多數意見反對系爭請求項具高度政策性須由立法程序解決之說法，主張認為對於政策影響力的爭論應加諸於政府的政治部門而不是法院。由 Brennan 大法官主筆、和 White、Marshall 以及 Powell 大法官加入的不同意見中有相反的論點：

"It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern."
「擴大或縮小專利法的範圍是國會的職責，不是法院。尤其當本案請求給予專利的組合物確實特別涉及公益。」

The debate about institutional competency in Chakrabarty was resolved by the majority on the basis that the statutory authority conferred on the courts by Congress under 35 USC §101 required an approach to patentability unconstrained by policy considerations. In Australia, the Parliament has left it to the courts to carry out a case-by-case development of a broad statutory concept according to the common law method in a representative democracy.
關於部門權限的爭論在 Chakrabarty 中，多數意見基於國會透過立法授權法院，應根據

35 USC §101 具可專利性要件的判斷不受政策考量的限制。在澳洲，議會在代議民主體制下，將此爭議交由法院根據普通法方法，在廣泛的法條空間下，採逐案認定之方式判斷。

p.18/ paragraph27

Myriad submitted that the Court ought to treat the impugned claims as claims for a chemical compound. It argued that there was "no jurisprudential basis or normative principle upon which claims to isolated nucleic acids should be treated differently from any other product claims." The Court should look to their subject matter and determine the question of patentability according to the principles in NRDC which had been affirmed in Apotex. That submission sought to locate the claims well within the established understanding of "manner of manufacture" in a way that would make normative considerations, which might inform the development of that concept, irrelevant. Properly construed, however, the claims are not within the established boundaries and wider considerations than Myriad's characterisation of them as an "artificially created state of affairs of economic utility" come into play.
Myriad 認為法院應該將系爭請求項視為化學組合物的請求項。Myriad 主張「並沒有對分離核酸的請求項與其他產品請求項應予差別對待的法理基礎或規範原則。」法院應審查請求項的內容，並根據已經為 Apotex 肯認 NRDC 中的原則，決定具可專利性與否的問題。該主張認為系爭請求項確實符合「生產方式」的既定理解，而如此理解會排除對該概念發展的規範性的考量。然而，在正確的理解下，系爭請求項並不在既定的理解範圍內，且應考量比 Myriad 將請求項定性為「人為創造具有經濟效用的狀態」以外更廣泛的因素。

p.18/ paragraph28

A number of factors may be relevant in determining whether the exclusive rights created by the grant of letters patent should be held by judicial decision, applying s 18(1)(a) of the Act, to be capable of extension to a particular class of claim. According to existing principle derived from the NRDC decision, the first two factors are necessary to characterisation of an invention claimed as a manner of manufacture:
法院在判斷依本法第 18(1)(a) 條由專利證書賦予的排他權是否能擴張請求項的特定類別時，應考量以下數個因素。根據從 NRDC 判決得出的現有原則，將主張保護的發明定性為生產方式時，應考量以下第一和第二個因素：

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action.
1. 主張保護的發明是否用於產品製造，或由於人的行為而產生結果的程序。

2. Whether the invention as claimed has economic utility.
2. 主張保護的發明是否具有經濟效用。

When the invention falls within the existing concept of manner of manufacture, as it has been developed through cases, they will also ordinarily be sufficient. When a new class of claim involves a significant new application or extension of the concept of "manner of manufacture", other factors including factors connected directly or indirectly to the purpose of the Act may assume importance. They include:
一般而言，當發明確實符合透過判決所建立的、現下的生產方式概念時即為已足。當新的請求項類別涉及「生產方式」概念重要的新理解或擴大時，其他因素，包含直接或間接和本法目的相關的因素，即屬重要。其中包含：

3. Whether patentability would be consistent with the purposes of the Act and, in particular:
3. 具可專利性是否需符合本法目的，特別是：

3.1 whether the invention as claimed, if patentable under s 18(1)(a), could give rise to a large new field of monopoly protection with potentially negative effects on innovation;
3.1 主張保護的發明，如果根據第 18(1)(a) 條具可專利性，是否造成新的、廣大的壟斷權保護範圍，而對創新有潛在的負面影響；

3.2 whether the invention as claimed, if patentable under s 18(1)(a), could, because of the content of the claims, have a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee;
3.2 主張保護的發明，如果根據第 18(1)(a) 條具可專利性，是否因為請求項的內容，在授予專利權人專有權利的內容之外的活動造成寒蟬效應；

3.3 whether to accord patentability to the invention as claimed would involve the court in assessing important and conflicting public and private interests and purposes.
3.3 授予主張保護的發明具可專利性，是否涉及法院評估公共和私人利益重大衝突以及目的。

4. Whether to accord patentability to the invention as claimed would enhance or detract from the coherence of the law relating to inherent patentability.
4. 授予主張保護的發明具可專利性是否會增強或減弱固有具可專利性的法律一致性。

5. Relevantly to Australia's place in the international community of nations:
5. 關於澳洲在國際社會的地位：

5.1 Australia’ s obligations under international law;
5.1 澳洲的國際法義務

5.2 the patent laws of other countries.
5.2 其他國家的專利法。

6. Whether to accord patentability to the class of invention as claimed would involve law-making of a kind which should be done by the legislature.
6. 授予主張保護發明的類別具可專利性是否涉及應由立法機關立法的國會保留範圍。

Factors 3, 4 and 6 are of primary importance. Those primary factors are not mutually exclusive. It may be that one or more of them would inform the “generally inconvenient” limitation in s 6 of the Statute of Monopolies. It is not necessary to consider that question given that no reliance was placed upon that proviso. They are nevertheless also relevant to the ongoing development of the concept of “manner of manufacture”.
第 3、4、6 因素是最重要的。這些主要因素並不互相排斥。可能是其中一個或多個因素將影響壟斷法第 6 條中「普遍不便性（generally inconvenient）」限制。壟斷法第 6 條並未要求考量第 3 到第 6 因素。但這些因素仍與「生產方式」概念的持續發展有關。

p.19/ paragraph29

Factors 1 and 2 have been discussed in the light of NRDC. The purpose of Australian patent legislation has been discussed in general terms in decisions of this Court. At a functional level, it can be defined narrowly by what the Act does — it confers upon a patentee, in return for disclosure of his or her invention, a limited monopoly at the expiration of which an invention is available to the public at large. That function may be expressed as an objective but it serves the larger purpose of encouraging innovation by means which do not stifle it. The inventive step which emerged as an independent requirement from the general limiting criterion of want of subject matter “reflected the balance of policy considerations in patent law of encouraging and rewarding inventors without impeding advances and improvements by skilled, non-inventive persons.” It follows that the purpose of the Act would not be served by according patentability to a class of claims which by their very nature lack well-defined boundaries or have negative or chilling effects on innovation. There may also be flow-on consequences for the balance that the Act seeks to strike and the coherence of the law as developed by judicial decision in giving effect to the purposes of the law. If there be a significant risk of such a consequence, the existence of that risk will weigh against inherent patentability.
第 1 和第 2 因素已參考 NRDC 案所揭示的意旨討論。本院歷來判決已對澳洲專利立法目的有過一般性討論。在功能層面上，專利可經由本法作用狹義定義為—將壟斷權授予專利權人，換取專利權人揭露其發明，在限制壟斷到期後，公眾可得使用該發明。

這個功能本身是個目標，但它更重要的目的是藉由不抑止創新的手段來達成鼓勵創新。進步性作為專利權標的一般限制標準中的獨立要件，反映「專利法的平衡政策，鼓勵和獎勵發明者，但不妨礙其他有能力的非發明者做成改良。」由此可知，授予一個本質上欠缺明確界線、或對於創新有負面影響或寒蟬效應的請求項類別具可專利性，將無法達成本法之目的。對本法試圖達成的平衡，及由法院判決所建立的法一致性，也可能會有後續影響。如果後續之影響有重大風險，即應與固有的具可專利性衡量。

p.20/ paragraph30

Coherence and the limits of the judicial function were both relevant in the determination in Apotex that methods of medical treatment can be inherently patentable. Having regard to the established patentability of pharmaceutical products, the exclusion of treatments using such products was anomalous and had no stable logical or normative basis. Their inclusion was consistent with the existing application of the law and served to enhance its coherence.
在 Apotex 一案中判斷治療方法本質上具可專利性，與司法權功能的一致性和限制有關。考量藥物產品既存的具可專利性，將使用藥物產品治療方法排除應屬例外，也欠缺穩固的邏輯或規範根據。【反之，[1]】將他們納入可專利性之範圍則符合現行法的適用，也增強法律一致性。

(iii)Legislative history.

(iii) 立法沿革

p.23/ paragraph36

Myriad submitted that what it called "the legislative history" did not support any implied "exclusion" of isolated DNA or RNA sequences from patentability. It relied upon the following events:
Myriad 主張其所謂的「立法沿革」並不支持將分離 DNA 或 RNA 序列隱含地「排除」於具可專利性之外。其植基於下列事件：

- The rejection in the Senate of an amendment to the Patents Bill 1990, which would have excluded genes from patentability, whether derived from cells or chemically synthesised.
- 參議院拒絕 Patents Bill 1990 的修正案，該修正案排除基因具可專利性—不論基因是從細胞取得的或是化學合成的。

- The rejection by the Legal and Constitutional Affairs Legislation Committee of the Senate of a Private Members' Bill, the Patent Amendment (Human Genes and Biological Materials) Bill 2010 .

[1] 【】係譯者為語意通順而附加。

• 參議院法律及憲法事務委員會拒絕普通議員法案 (Private Members' Bill[2])，2010 年專利修正草案〔人類基因和生物材料 (Biological Materials)〕。

Myriad also referred to the Report of the Australian Law Reform Commission on gene patenting, published in 2004 ("the ALRC Report"), and its conclusion that "the ALRC considers that a new approach to the patentability of genetic materials is not warranted at this stage in the development of the patent system". Myriad's submissions on legislative history rested upon the premise, derived from debates on the failed amendments and the recommendation in the ALRC Report, that this case is about exclusion from patentability of an otherwise patentable invention. In its written submissions, Myriad said that:
Myriad 也提及澳洲法律改革委員會 (the Australian Law Reform Commission) 於 2004 年出版基因專利報告 (「 ALRC 報告」)，其結論為「澳洲法律改革委員會認為，在專利制度發展的現階段，尚不應對基因遺傳物質具可專利性的判斷採取新的認定方法（new approach）」。Myriad 在立法沿革的主張，是自前述修正案和 ALRC 報告均未通過的事實推論，進而主張這個案件係關於是否將本具可專利性的發明排除於專利權外。在其訴狀，Myriad 說道：

"Parliament has expressly declined to enact any such exclusion on more than one occasion. This making of a conscious decision not to act sets this area apart from mere silence by the legislature, which might be characterised as the legislature leaving the field to the Courts for resolution."
「議會已經不只一次明示拒絕將任何此類排除立法。這個有意識決定的不行動，有別於可以被視為立法機關將該領域交由法院解決的單純沉默。」

p.24/ paragraph37

This Court is not concerned in this appeal with "gene patenting" generally, but with whether the invention as claimed in Claims 1 to 3 falls within established applications of the concept of manner of manufacture. If it does not, then the question is one of inclusion not exclusion. The legislative history cannot be read as impliedly mandating the patentability of claims for inventions relating to isolated nucleic acids coding for particular polypeptides. The legislative history does not assist the Court in answering the question posed in this appeal.
本法院在本上訴並不處理「基因是否具可專利性」的一般問題，而是請求項 1 至 3 中主張保護的發明，是否符合既定生產方式概念所適用的範圍。若否，那問題即為是否包含而非是否排除。立法沿革並未暗示而逕自將具可專利性賦予能編碼產出特定多肽之分離核酸的發明。立法沿革不能協助法院回答本上訴提出的問題。

p.24/ paragraph38

Against that general background, the relevant science, the patent specification and the im-

[2] http://lawyer.get.com.tw/dic/DictionaryDetail.aspx?iDT=71025

pugned claims can be considered.
在這背景下，可以考量相關科學、專利說明書和系爭請求項。

(xii)　Isolated nucleic acid — composite or extract?

(xii) 分離核酸－合成物還是提取物？

p.34/ paragraph72

There is no claim in the patent for the process of isolation nor could there be as no new process is disclosed. However, in answer to questions from the Court, counsel for Myriad focussed upon an aspect of the evidence about isolation processes in order to deflect a suggestion that an isolated nucleic acid can be viewed as a "piece" of naturally occurring DNA or RNA. He contended that isolation involved alteration of the order of the relevant nucleotides and their reassembly in the order in which they had been placed in the cell. That proposition was supported by reference to the evidence of the expert witness, Dr Suthers. Dr Suthers had agreed that a conventional way of extracting a gene sequence, as distinct from synthesising it, would involve breaking the hydrogen bonds between the bases and breaking some covalent bonds to release the extract. He also agreed that in the mid-1990s a 100,000 base sequence would be broken up into smaller pieces which could then be amplified and stitched together physically or "conceptually".
本案中並未請求分離過程的專利，也未揭露新的製程。然而，在對法院提問的回答中，Myriad 的辯護人聚焦於「有一個分離過程」的證據，以迴避將核酸視為自然存在於 DNA 或 RNA 中的「一段」的見解。他爭論分離的過程涉及改變相關核甘酸的序列以及重新組成核甘酸原先在細胞中的序列。這一主張有專家證人 Suthers 博士證言的支持。Suthers 博士同意提取基因序列的常見方式和合成不同，釋出提取物必須破壞鹼基間的氫鍵以及一些共價鍵。他也同意在 1990 年代中期，一個十萬個鹼基序列可分解成較小的片段，然後可以物理上或「概念上」擴大和拼接在一起。

p.35/ paragraph73

The preceding argument has some similarity to Myriad's submission to the primary judge that Dr Suthers' evidence supported the proposition that there would be at least some breaking of the covalent cells in the sugar phosphate backbone as a result of the isolation process. The primary judge said:
前述論點和 Myriad 其在初審的主張有相似之處，Suthers 博士的證言支持該主張，即分離過程至少會破壞一些在糖磷酸骨架中的共價鍵。初審法官說：

"It is not apparent to me that every isolated DNA sequence within the scope of the claims must have had at least some covalent bonds broken as a result of the isolation process. Nor would I imply any such requirement into the claims merely because, in Dr Suther's experience, this is what occurs. To interpret the disputed claims in this way would require me to impose an impermissible

gloss upon the words of the claim."
「對於我來說，在請求項範圍內每一分離的 DNA 序列，於分離過程中皆至少破壞一些共價鍵，並非顯而易見之事。我也不會僅因為分離過程中必然破壞共價鍵 (如 Suthers 博士所證言)，即暗示在請求項中須有該要件。以這種方式解釋系爭請求項，是對請求項的內容採取法所不容許的解讀。」

Nor, as previously noted, are the claims subject to any process based limitation involving the breaking up and physical stitching together of the sequences comprising the isolated nucleic acids which are the products the subject of the claims. The "conceptual" stitching together, which may be regarded as the ordered compilation of information defining the relevant sequence, falls outside the claims entirely. The claims encompass molecules comprising isolated nucleic acids containing coding nucleotides arranged in the same sequence as appears in the DNA from which they were derived, whether or not introns and other non-coding sections have been removed from the relevant stretch of that DNA.
請求項，如前所述，為透過分解及物理性拼接所構成分離核酸的序列—即該請求項之產品，亦不應受任何製程上的限制。而「概念上」拼接在一起，可視為訊息的有序組合（ordered compilation）而構成的相關序列，則完全不在請求項之內。請求項包含構成分離核酸的分子，分離核酸包含與其來源之 DNA 相同序列的編碼核甘酸，無論內含子和其他非編碼部分是否已從該 DNA 的相關區段去除。

(xiii) The primary judge's decision.

(xiii) 初審判決

p.36/ paragraph74

For the primary judge, the issue of patentability turned on:
對初審法官，爭點為具可專利性：

"whether an isolated nucleic acid, which may be assumed to have precisely the same chemical composition and structure as that found in the cells of some human beings, constitutes an artificial state of affairs in the sense those words should be understood in the present context."
「於本案情狀下，若假定分離核酸與人類細胞有完全相同的化學成分和結構，則分離核酸是否構成人為狀態[3]？」

That approach, as observed earlier, involves application of the verbal formula in NRDC and the apparent assumption, no doubt derived from the way the case was framed before his Honour, that it was a sufficient condition of inherent patentability.
如前所述，本案初審的分析方式無疑地涉及 NRDC 一案中語言公式的適用、且假設若

[3] 此處原文為 artificial state of affairs，非如前原文 artificially created state of affairs，翻譯為「人為創造狀態」，然應為相同意思。

符合該公式即具可專利性。

p.36/ paragraph75

His Honour observed that isolated nucleic acids do not exist inside the cell and their isolation required "immense research and intellectual effort." Despite his Honour's reliance upon the "artificial state of affairs" formula, the influence of wider purposive considerations was apparent in his judgment, including the observation that:
該法官認為細胞內不存在分離的核酸，且核酸的分離須「大量研究和智慧投入」。雖然該法官依據「人為創造狀態[4]」的公式，但在他的判斷中，顯然包含更廣泛的目的性考量，包含：

"It would lead to very odd results if a person whose skill and effort culminated in the isolation of a micro-organism (a fortiori, an isolated DNA sequence) could not be independently rewarded by the grant of a patent because the isolated micro-organism, no matter how practically useful or economically significant, was held to be inherently non-patentable."
「若認為分離的微生物不具固有可專利性，則在個人的技術和努力下成功分離一個微生物（更不用說分離一個 DNA 序列），無論多實際有用或有經濟效益，都不能單獨地獲得專利作為獎勵，是非常奇怪的。」

p.36/ paragraph76

His Honour cited the practice of the Australian Patent Office, and the rejection by Parliament of proposed amendments precluding gene sequences from patentability. Those matters led to no firm conclusion beyond a finding that it was not the intention of Parliament to deal with the issue of gene patenting by way of express exclusion but to leave it to the courts to apply the law as settled in NRDC and other relevant authorities. His Honour referred to patent laws of the European Union as permitting patentability of gene sequences. It is difficult to discern how those matters could have been related to a simple categorical application of the "artificial state of affairs" criterion. Their relevance can only have been to wider considerations of the kind discussed earlier in these reasons although how they were used was not apparent from his Honour's reasons.
該法官引用澳洲專利局的做法，以及議會拒絕排除基因序列具可專利性之提案。這些事件只能說明國會無意明示排除基因具可專利性，而應將基因專利的問題交由法院適用 NRDC 案以及其他相關法律標準。該法官援引歐盟專利法制承認基因序列具可專利性。很難看出這些事件如何和「人為狀態[5]」標準的適用有關。其中關聯性難以從該法官的判決論證中看出，而必須從前述所討論的、更廣泛的因素考量。

4　同註 3。
5　同註 3。

p.37/ paragraph77

In the event, his Honour concluded that each of the disputed claims was to "a manner of manufacture as that expression should now be understood."
該法官認為，每一系爭請求項都「可理解為生產方式。」

(xiv) The decision of the Full Court.

(xiv) 上訴審判決

p.37/ paragraph78

The Full Court described the impugned claims as claims "for a product set within a context of invention described in the specification: a context of development, through research and work, of the knowledge of the mutations or polymorphisms in question, and of the finding of the gene in question." Their Honours emphasised the character of the claims as relating to "the nucleic acid as isolated from the cell" and differences between the claimed product and the "naturally occurring product".
上訴審敘述系爭請求項為「請求專利說明書所述發明範圍中的產物：通過研究和作用（work）獲取變異或多型性的知識、發現肇因之基因，及其過程。」此審法官強調該請求項之性質與「從細胞中分離的核酸」相關，並主張保護的產物和「天然產物」不同。

p.37/ paragraph79

Their Honours referred at some length to the decision of the Supreme Court of the United States in Association for Molecular Pathology v Myriad Genetics Inc. That decision was concerned with the application of 35 USC §101 to claims differently expressed from those impugned in this case:
其法官曾以相當篇幅論及美國最高法院 Association for Molecular Pathology v Myriad Genetics Inc 一案之判決。該判決關於 35 USC §101 於請求項之適用，其請求項與本案系爭請求項描述不同：

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID No:2.
1. 一個能編碼 BRCA1 多肽的分離 DNA，所述多肽具有 SEQ ID No:2. 所列的氨基酸序列。

2. The isolated DNA of claim 1 wherein said DNA has the nucleotide sequence set forth in SEQ ID No:1 ("the Myriad claims").
2. 請求項 1 分離 DNA，其中 DNA 係指具有 SEQ ID No:1 所列的核甘酸序列 (「Myriad 請求項」)。

The Supreme Court had accepted that the creation of a cDNA sequence from mRNA resulted in an exon-only molecule that was not naturally occurring and was therefore patentable. The Myriad claims, however, fell squarely within a "law of nature" exception. While Myriad had discovered the location of the BRCA1 gene that discovery did not lend to the BRCA1 gene the character of a new composition of matter within 35 USC §101.
美國最高法院同意從 mRNA 作成只含有外顯子的 cDNA 序列分子，不是自然存在的，因此具可專利性。然而，Myriad 的請求項正是「自然法則」的例外。雖然 Myriad 已經發現 BRCA1 基因的位置，但是該發現並未使 BRCA1 基因具備 35 USC §101 中新組合物之特性。

p.38/ paragraph80

The Full Court preferred the reasoning of the United States Court of Appeals for the Federal Circuit in Association for Molecular Pathology v United States Patent and Trademark Office, which had been overturned by the Supreme Court. Their Honours characterised that reasoning as based on an analysis of the products as products and not of the information that they contained. They held that, consistently with NRDC and Australian law, their analysis should focus on differences in structure and function effected by the intervention of man and not on the similarities.
上訴審更傾向於美國聯邦巡迴上訴法院於 Association for Molecular Pathology v United States Patent and Trademark Office 一案中的判決理由，但（美國）最高法院推翻該判決。上訴審法官敘述其判決理由是基於分析該產物為產品，而不是產物所包含的訊息。與 NRDC 和澳洲的法律一致，他們認為分析應著重在人為介入所產生結構與功能上之差異，而不是相似之處。

p.38/ paragraph81

Outside the logical framework which they had defined for their analysis, their Honours adverted to the primary judge's consideration of Australian Patent Office practice, the ALRC Report, and the legislative history. They also referred to the Executive Government's response to the ALRC Report, including its acceptance of the recommendation that the Act not be amended to exclude genetic materials and technologies from patentable subject matter. They said:
在邏輯框架之外，上訴審法官分析了初審法官考量澳洲專利局的做法、ALRC 報告和立法沿革。上訴審法官也提到行政機關對於 ALRC 報告的回應，包含接受專利法不應修改為排除基因材料和技術不具可專利性標的之建議。他們說：

"While these legislative matters do not affect what constitutes patentable subject matter under the rubric of 'manner of manufacture', Parliament has considered, and has specifically declined, to exclude purified and isolated gene sequences from the scope of patentable subject matter."

「雖然這些立法事件並不影響根據『生產方式』的標準什麼會具可專利性，但議會已仔細考慮並明確拒絕將純化和分離的基因序列排除於具可專利性範圍之外。」

p.39/ paragraph82

Before the Full Court, Ms D' Arcy submitted that isolated nucleic acid was not materially different to cellular nucleic acid and that naturally occurring DNA and RNA, even in isolated form, are products of nature that could not form the basis of a valid patent. Myriad, on the other hand, contended that its claims were for a product consisting of an artificial state of affairs providing a new and useful effect of economic significance, and that isolated nucleic acid differed from the nucleic acid found in a human cell chemically, structurally and functionally.
於上訴審，D' Arcy 女士主張分離的核酸和細胞核酸實質上沒有不同，即使是分離的型態也是天然存在的 DNA 和 RNA，也是自然的產物，不能作為一個有效專利的基礎。另一方面，Myriad 則認為，其請求項是由人為狀態[6]構成的產品，其提供具有經濟上意義新且有用的結果，以及分離的核酸與人類細胞中發現的核酸在化學上、結構上和功能上不同。

p.39/ paragraph83

As previously observed, in its concluding paragraphs, the Full Court eschewed the relevance of policy, moral or social reasons for the exclusion of patents for gene sequences. Like the majority in Chakrabarty, their Honours said of those considerations:
如前所述，上訴審在其結論部分迴避了排除基因序列專利之政策、道德或社會考量因素。和 Chakrabarty 一案多數意見一樣，該案法官認為：

"It is not a matter for the court, but for Parliament to decide. Parliament has considered the question of the patentability of gene sequences and has chosen not to exclude them but to make amendments to the Act to address, in part, the balance between the benefits of the patent system and the incentive thereby created, and the restriction on, for example, subsequent research."
「這不是法院須處理的問題，而是由議會決定。議會考量了基因序列具可專利性的問題，並選擇不排除它們，而是修改該法案，部分處理專利制度的利益與由此產生的鼓勵和限制（例如隨後的研究）之間的平衡。」

They characterised the subject matter of the claims as :
他們將這些請求項的內容定性為：

- a compound, not information;
- 一個組合物，而不是訊息；

[6] 同註 3。

- an isolated nucleic acid, which is taken out of the genome and removed from the cell and is unable to be the subject of cellular processes of transcription and translation;
- 分離的核酸，是從基因組中取出並從細胞中分離，且不能進行轉錄和轉譯；

- containing the code for a mutant or polymorphic protein; and
- 含有變異或多型性蛋白的密碼；以及

- containing a sequence identified by comparison with tables created following extensive research describing the location of the mutations or polymorphisms in DNA.
- 含有一個與經大規模研究描述 DNA 中變異或多型性的位置所建立的表比較後識別出的序列。

p.40/ paragraph84

It was common ground before the Full Court that the isolated nucleic acids had valuable economic uses. In their reasons, their Honours said:
在上訴審，分離的核酸具有重要的經濟用途已有共識。在理由中，上訴審法官說道：

"The isolation of the nucleic acid also leads to an economically useful result — in this case, the treatment of breast and ovarian cancers. This is surely what was contemplated by a manner of new manufacture in the Statute of Monopolies."
「核酸的分離亦導致經濟上有用的結果－本案中，是乳癌和卵巢癌的治療。這當然是壟斷法中新生產方式必須仔細考慮的。」

The Full Court concluded that the isolated nucleic acids, including cDNA, had resulted in an artificially created state of affairs for economic benefit and that the claimed product was properly the subject of letters patent.
上訴審的結論是，分離的核酸，包含 cDNA，是一個人為創造的狀態且具有經濟利益的結果，以及主張保護的產品可以核發專利證書。

p.40/ paragraph85

The passage quoted in the preceding paragraph, which appears to refer to the process of "isolation", does not disclose a pathway to patentability of the invention as described in Claims 1 to 3. That is so even if they were to be characterised as product claims simpliciter, a characterisation which, as appears below, we do not accept. The economic significance necessary to the patentability of an "artificially created state of affairs" in the sense used in NRDC is not demonstrated by stating that the artificially created state of affairs is a step along the way to a process or method itself claimed as an artificially created state of affairs of economic significance.

前面所提及似乎在談論「分離」過程的段落，並無法說明請求項 1 至 3 所述者具可專利性。即使直接把它們定性為產品請求項也是如此，如下所示，我們並不接受該定性。NRDC 一案所使用，具有經濟意義為一個「人為創造狀態」具可專利性所必要，此並未表明人為創造狀態是一個符合製程或方法之途徑、製程或方法係指一個人為創造具有經濟意義的狀態。

(xv)Conclusions.

(xv) 結論

p.41/ paragraph86

Myriad submitted, as the Full Court had held, that its claims are for a product. To assess patentability, it said, they must be construed in the same way as any other claim for an invention which is a product. The product was "a chemical compound [which] has no counterpart in nature." That characterisation of the claims superficially accords with their form.
Myriad 主張，正如上訴審所認定，其請求項是針對產品。為了評估具可專利性，系爭請求項必須和任何其他發明且為產品的請求項，以相同的方式來理解。該產品是「一種化學組合物，且在自然界中無相似之物。」前開對該請求項之描述，僅係草率地依其形式為之。

p.41/ paragraph87

The approach taken by the Full Court and urged by Myriad involves an apparently straightforward characterisation based on the formal terms of the patent identifying the isolated nucleic acids as products which, notwithstanding their derivation from naturally occurring DNA, have been brought into existence by human artifice and, in that sense, "made". So characterised, and without further inquiry into the breadth of the claims or their substance, they could be seen to fall comfortably within principles attracting characterisation as a manner of manufacture. None of the purposive or policy factors mentioned earlier in these reasons need be considered on that approach.
上訴審以及 Myriad 所極力主張的分析方式，涉及一個顯然過於直截了當地定性，即基於專利形式要件，認為分離的核酸是產品，雖然它們源於自然存在的 DNA，但經過人類介入而得以存在，符合「生產（made）」的意義。所以，如此定性，未進一步細查請求項的範圍或本質，可無疑地視其符合生產方式的概念。該分析方式無需考量前述提及之目的性或政策等因素。

p.41/ paragraph88

Identification of the subject matter of the claims as a class of chemical compounds is the premise upon which the Full Court's conclusion is based. It is a premise which, with respect, elevates

form over substance to the detriment of the developmental function entrusted to the Court as explained in NRDC and reflected in the continuing use of the "manner of manufacture" formula in s 18(1)(a) of the Act.
將請求項的內容作為一類化學組合物，是上訴審結論所依據的前提。如 NRDC 一案所闡述，法院被賦予解釋本法第 18(1)(a) 條「生產方式」公式之職能，然該上訴審所依據之前提，使法院優先以形式而非實質判斷，不利法院發揮前述職能。

p.41/ paragraph89

The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide. That sequence can properly be described as "information", the ordinary meaning of which includes:
主張保護發明中的密碼（code），指的是在細胞環境中最終能轉譯成 BRCA1 多肽的核甘酸序列。該序列可正確地描述為「訊息」，其意義通常包含：

"Without necessary relation to a recipient: that which inheres in or is represented by a particular arrangement, sequence, or set, that may be stored in, transferred by, and responded to by inanimate things".
「與受試者沒有必然關係，訊息生來即存在，其可由一個特定的排列、序列或組合所表現，而可經由無生命體儲存、轉化及產生反應。」

Used in that sense, the information stored in the sequence of nucleotides coding for the mutated or polymorphic BRCA1 polypeptide is the same information as that contained in the DNA of the person from which the nucleic acid was isolated. It is the existence of that information which is an essential element of the invention as claimed. The product is the medium in which that information resides. That characteristic also attaches to cDNA, covered by the claims, which is synthesised but replicates a naturally occurring sequence of exons.
依前述定義，該儲存於核甘酸序列中變異或多型性的 BRCA1 多肽密碼的訊息，與該分離核酸的人的 DNA 中，所包含的訊息相同。該訊息的存在是主張保護的發明不可或缺的要素。該產品是訊息所在的媒介。請求項所涵蓋的 cDNA 亦符合前述特性，cDNA 是合成物但其是複製自然存在的外顯子。

p.42/ paragraph90

Ms D' Arcy submitted that none of the chemical, structural or functional differences between isolated nucleic acids and nucleic acids in the cellular environment, relied upon by Myriad, plays any part in the definition of the invention as claimed in each of the claims. She invoked the observation of the plurality opinion of the Supreme Court of the United States in Myriad directed to a common feature of the claims in issue in that case and the claims in issue in this case :

D’ Arcy 女士主張，Myriad 所主張分離的核酸和細胞環境中的核酸之間，在化學上、結構上和功能上的差異，並未在主張保護發明的個別請求項中起到任何界定作用。她援引美國最高法院在 Myriad 案的多數意見，針對該案和本案系爭請求項的共同特徵：

“Myriad’ s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.”
「Myriad 的請求項並非以化學組合物呈現，亦非於分離 DNA 特定部分所產生的化學變化結果。相對地，該請求項應理解為 BRCA1 和 BRCA2 基因編碼的遺傳訊息。」

That characterisation, so far as it emphasises the focus of the claims on genetic information, is applicable to the claims in this case and, contrary to the view of the Full Court, should be accepted.
我們應接受將該請求項理解為遺傳訊息之特性（此觀點與上訴審相反），且適用於本案的請求項。

p.42/ paragraph91

Ms D’ Arcy also engaged with the finding by the Full Court that the isolated nucleic acids were patentable as “an artificially created state of affairs”. Engaging with that criterion in this case places the question of patentability in too narrow a frame. It invites debates about the application of categories such as “products of nature” versus “artificially created products” which may be distracting from the central issue, that is whether an essential integer of the claims, the genetic information, takes them outside the category of that which can be “made”. But even if the criterion of an “artificially created state of affairs” were to define the area of discourse in this case, the fact of the existence of the requisite mutations or polymorphisms is a matter of chance. It is not something “made”. It is not “artificially created”.
上訴審認為分離的核酸為「一個人為創造的狀態」故具可專利性，D’ Arcy 女士也就此提出爭執。本案依該標準處理窄化了具可專利性的問題。其引發像是「自然產物」抑或「人為創造的產品」等關於類型適用的爭論，這可能會模糊爭點，即請求項中核心的完整技術（essential integer），遺傳訊息，是否符合可「生產」的類型範圍。即使「人為創造的狀態」的標準能夠在本案中界定所討論的範圍，然而變異或多型性是否存在純屬機率。這不是「生產」出的東西。這不是「人為所創造」的。

p.42/ paragraph92

There are perhaps two ways of looking at the role of genetic information in characterising the subject matter of the claims. One way is to say that the chemical formula of any given isolated nucleic acid is defined, in part, by the sequence of nucleotides which it reproduces and, in that sense, is

defined by the information embodied in that sequence. Another way is to say that the particular chemical compound embodies and conveys the information. The latter approach gives the priority to the informational aspect which its importance to the utility of the claimed invention warrants.
可能有兩種方式來理解遺傳訊息於定性該請求項標的的作用。一種方式是說，任何給定的分離核酸，其化學式部份地由複製的核甘酸序列所定義—故，在此意義上，也是由該序列所體現的訊息所定義。另一種方式是說，特定的化學組合物體現並傳遞該遺傳訊息。後一種方式著重訊息面向，對主張保護發明之利用是重要的。

p.43/ paragraph93

When proper regard is paid to their emphasis on genetic information, the subject matter of the claims lies at the boundaries of the concept of "manner of manufacture". That it does lie at the boundaries is further evidenced by the odd consequence that if the claims are properly the subject of a patent, the patent could be infringed without the infringer being aware of that fact. That consequence coupled with the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and inventors.
當我們所關心的重點為遺傳訊息，該請求項標的會落在「生產方式」概念的模糊地帶。若該請求項確實具可專利性，則侵權人可能於無意識間侵害該專利—這種奇怪的狀況也說明該請求項標的確實落在「生產方式」概念的模糊地帶。該狀況再加上大到無法量化的分離核酸類別（其帶有必要訊息），可能引起對合法創新活動之寒蟬效應，產生壟斷權事實上（de facto）的暈影（penumbral），妨礙合法改良及發明行為。

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Although it may be said in a formal sense that the invention as claimed, referring to isolated nucleic acids, embodies a product created by human action, that is not sufficient to support its characterisation as a manner of manufacture. The substance of the invention as claimed and the considerations flowing from its substance militate against that characterisation. To include it within the scope of a "manner of manufacture" involves an extension of that concept, which is not appropriate for judicial determination. Further, to include this class of claim within that concept would not contribute to coherence in the law as was the case in Apotex. Nor do Australia's international obligations and the differently framed patent laws of other jurisdictions, which were referred to earlier in these reasons, support the conclusion that this class of claim should fall within the concept.
儘管在形式意義上，與分離核酸相關而主張保護的發明，是人的行為產生的產品，仍不足以支持其具有生產方式的特性。因為該主張保護發明的本質、以及由其本質產生的考量因素，皆使其不符合該特性。將其納入「生產方式」的範圍涉及該概念的擴大，

並不適合由法院來決定。再者，將該請求項類別包含在該概念內，將不會像 Apotex 一案一樣有助於法律一致性。又如前述，澳洲的國際法義務及其他管轄權下的專利法，都不支持視該請求項類別符合此概念的結論。

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The invention as claimed in Claims 1 to 3 does not meet the requirement of s 18(1)(a) and the appeal should be allowed.
主張保護發明的請求項 1 至 3 不符合本法第 18(1)(a) 條之要件，應准許本上訴。

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The following orders should be made:
應作成下述判決：

1. Appeal allowed.
1. 上訴准許。

2. Set aside paragraph 1 of the order of the Full Court of the Federal Court of Australia made on 5 September 2014 and, in its place, order that:
2. 撤銷澳洲聯邦法院上訴審於 2014 年 9 月 5 日作成的判決第一段，並在此作出以下判決：

(a) the appeal be allowed; and
(a) 上訴准許；以及

(b) paragraph 1 of the order of Nicholas J made on 15 February 2013 be set aside and, in its place, order that claims 1, 2 and 3 of Australian Patent No 686004 be revoked.
(b) 撤銷 Nicholas 於 2013 年 2 月 15 日作成判決的第一段，並在此判決澳洲專利 686004 號請求項 1、2 以及 3 無效。