RESMED

Committee Secretary
Senate Legal and Constitutional Committees
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

25 February 2011

Dear Sir/Madam

RE: Patent Amendment (Human Genes and Biological Materials) Bill 2010

ResMed is a leading developer, manufacturer and distributor of medical equipment for treating, diagnosing, and managing sleep-disordered breathing and other respiratory disorders. The company is dedicated to developing innovative products to improve the lives of those who suffer from these conditions and to increasing awareness among patients and healthcare professionals of the potentially serious health consequences of untreated sleep-disordered breathing.

Please find attached a Submission regarding the Bill.

Yours sincerely

Paul A. GREEN PhD MIP BE BSc

SUBMISSION REGARDING
Patent Amendment (Human Genes and Biological Materials) Bill 2010

1. Summary

In our opinion, enactment of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 ('the Bill') would change, rather than clarify Australian law on patent-eligible subject matter.

The change would add uncertainty to the scope of patentable subject matter in practice, particularly in relation to the term "substantially identical".

The change would cause Australian law to diverge from patent law in Europe, the United States, Japan and Korea. It is not clear that the change would be commensurate with the scope of exclusions to patentability permitted under Article 27 of the TRIPS Agreement.

The change would have an impact on patents in a range of fields outside medical treatment, including food production, chemical production and waste treatment.

The decision of the Australian High Court in the NRDC case on patent-eligible subject matter together with the tests of novelty, inventive step and utility provide a framework to decide which products and processes should be patented. The mechanism of compulsory licences and/or patent pools can be used to address many concerns raised about access to patented products and processes.

We do not support enactment of the Bill in its current form.

2. Introduction

The invention, discovery and widespread availability of new, low-cost technologies has transformed human lives over the last few hundred years. New technologies have had a dramatic effect on improving human health, especially since the time of the Industrial Revolution[1].

Australia's patent system has direct roots back to the Statue of Monopolies of 1623/1624, and indirect roots to earlier systems, such as the Statute of Venice of 1474[2]. While there is much familiar in these older laws, there are also differences. Ultimately we need to decide what form of laws best fit modern Australian society to ensure that the Australian Patents Act is compatible with continuing the transformation of technology and improvement of human health.

Just as the patent system is not new, its interaction with medicine and medical treatment is also not new. We would like to illustrate this with two examples. The first is insulin, and the second, antibiotics.

Insulin

In January 1922, when news spread that diabetic patients could be treated by Dr Frederick Banting with pancreatic extract - insulin - it "sparked an unquenchable demand from diabetics around the world somehow to receive a supply of this new 'wonder drug' immediately"[3]. For his work on diabetes, Dr Banting was knighted, shared a Nobel Prize[4], was elected a Fellow the Royal Society, and nominated as one of the top 10, "Greatest Canadians"[5]. Amongst other things, Dr Banting also worked on silicosis and cancer.

Dr Banting and his colleagues sought a patent and were awarded on 9 October 1923, US Patent 1,469,994. Claim 1 of that patent was:

> 1. A substance prepared from fresh pancreatic or related glands containing in concentrated form the extractive from the duct-less portion of the glands sufficiently free from injurious substances for repeated administration and having the physiological characteristics of causing a reduction of blood sugar useful for the treatment of diabetes mellitus.

Dr Banting sold the patent to the University of Toronto for $1[6].

The patent generated net royalties of about $2.4 million for the University which were used to fund research by Dr Banting and his colleagues. Two further patents generated a total of about $6.8 million which was also spent on research[7].

When insulin was first available from the Connaught Antitoxin Laboratories in Canada, the cost (in equivalent 2006 dollars) was $119 per 100 units. Over the next twenty years, Connaught was able to reduce the price to about $2.43, by increasing production capacities and higher yields[8].

In the 1970s, the price of Connaught insulin increased.

> "An important factor that made it more difficult for Connaught to absorb rising insulin production and other costs during the 1960s and 1970s was the loss of royalty income [upon their expiry] that had been generated by various insulin patents."[9]

Antibiotics

The Australian scientist, Dr. Howard Florey was awarded a Nobel prize in 1945 for his work heading a team of British scientists in isolating Penicillin. He was also knighted, and won many honours, including the Lister Medal of the Royal College of Surgeons and the Royal and Copley

Medals of the Royal Society, as well as honorary degrees from seventeen universities[10].

Florey did not seek a patent on his penicillin work, and shared it with US colleagues[11]. Subsequently, Moyer and others in the US patented methods for improved yields[12].

Florey is quoted[13] as saying:
"It has been a tradition amongst the medical profession not to patent anything with which they were associated. This was not done in the case of penicillin on the advice of certain eminent medical people in this country, and the nation has since had the greatest cause to regret it, as it has cost us very many millions of dollars and no doubt will go on doing so."

Later, when members of Florey's research team, Abraham and Newton, isolated the antibiotic cephalosporin[14] from a fungus growing in a sewage outfall in Sardinia, they did seek patents. One of these patents was US 3,093,638 with the title "Cephalosporin C", patented 11 June 1963. Claim 1 was:
1. A product of manufacture, the antibiotic substance, Cephalosporin C substantially free from Cephalosporin N; said Cephalosporin C containing carbon, hydrogen, oxygen, nitrogen and sulphur only and being a monoaminocarboxylic acid effective against both gram positive and gram negative bacteria; soluble in water and almost insoluble in ethanol and ether; the sodium salt having an ultra-violet absorption maximum at 260 mμ and an infra-red spectrum showing bands at 2.94μ, 3.06μ, 5.61μ, 5.77μ, 6.05μ, 6.29μ, 6.57μ, 7.17μ and 7.36μ; stable in aqueous solution at a pH of 2.5 and having a specific rotation $[\alpha]D^{20}$ of +103° in the form of its sodium salt.

Royalties from the portfolio of Cephalosporin patents were significant. Upon his death in 1999, an obituary[15] of Abraham reported:
The royalties from Cephalosporin C which flowed into the NRDC sustained it over its first two decades. Three Charitable Trust Funds were set up by Abraham to receive his royalties from which the university and many of Oxford's colleges and departments have benefited enormously. Many a young scientist has cause to thank Edward Abraham for providing so many junior research fellowships in Oxford colleges. The university benefited from the endowment of several chairs as well as from funds for the building of new laboratories. The Royal Society benefited from the endowment of the EPA Cephalosporin Fund Senior Research Fellowship.

The cases of insulin and cephalosporin both match the circumstances of the Bill. In both cases, isolated biological materials were patented.

One of the proponents of the Bill describe[16] those using the patent system thus as:
"a bunch of lawyers, bankers and people who are financially driven"

and further-
"… a disgrace' ... this ... has been for the last 30 years ... a legal trick played by clever patent attorneys"[17].

and further[18]
"That is why you have all these lawyers. I would shoot two of three lawyers, philosophically."

It is difficult to see Drs Banting, Florey, Abraham and Newton fitting this description. Not only were isolated materials patentable in the past, patent royalties were used not by those "financially

driven", but for further research and improved higher yielding production methods.

In this submission we present our understanding of current Australian and international patent laws, and compare that with the Bill. In particular we focus on the following questions:
1. What is current Australian law on the patentability of discoveries?
2. Would the Bill change the law if enacted?
3. How would "identical or substantially identical" be tested in practice?
4. How does the Bill compare with international law?
5. Should the Bill be enacted?

3. Statute, case law and the Bill

3.1 The Act, the Statute, and Australian Case law.

Section 18 of the Australian Patents Act 1990 (the Act) provides:

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

The Statute of Monopolies referred to in s18(1)(a) declares[19]

[I.] All Monapolies and all Commissions Graunts Licences Charters and tres patents heretofore made or graunted, or hereafter to be made or graunted to any person or persons Bodies Politique or Corporate whatsoever of or for the sole buyinge sellinge makinge workinge or usinge of any thinge within this Realme or the Dominion of Wales, or of any other Monopolies, or of Power Liberty or Facultie to dispence with any others, . . . , are altogether contrary to the Lawes of this Realme, and so are and shalbe utterlie void and of none effecte, and in noe wise to be putt in ure or execucion.

Section 6 is a proviso for future Patents for 14 years or less, for new Inventions.

VI. Provided alsoe That any Declaracion before mencioned shall not extend to any tres Patents and Graunt of Privilege for the tearme of fowerteene yeares or under, hereafter to be made of the sole working or makinge of any manner of new Manufactures within this Realme, to the true and first Inventor and Inventors of such Manufactures, which others at the tyme of makinge such tres Patents and Graunts shall not use, soe as alsoe they be not contrary to the Lawe nor mischievous to the State, by raisinge prices of Commodities at home, or hurt of Trade, or generallie inconvenient; the said fourteene yeares to be from the date of the first tres Patents or Grant of such priviledge hereafter to be made, but that the same shall be of such force as they should be if this Act had never byn made, and of none other.

Importantly for the present issues, the Statute contained further sections which *allowed* the following patents, grants and privileges:

9) Those held by Charters of London and other Corporations, Companies, Fellowships or Societies of Merchants;

10) Those concerning the digging, making or compounding of saltpeter[20] or gunpowder, or the casting or making of ordnance or shot for ordnance;

11) Those concerning the digging, compounding, or making of alum[21] or alum-mines;
12) Those concerning the selling, carrying, lading, disposing, shipping, venting, or trading;
of or for any sea-coals, stone-coals or pit-coals forth or out of the haven and river of Tyne; or concerning the ... selling, uttering, or retailing of wines to be drunk or spent in the mansion house or houses, or other place;
13) Those concerning the making of glass ... granted to Sir Robert Mansell, Knight, vice-admiral of England; [and] to ... to James Maxwell, Esquire, concerning the transportation of calf-skins;
14) Those concerning the making of smalt ... granted to Abraham Baker; ... or concerning the melting of iron ore and of making the same into cast works or bars with sea-coals or pit-coals granted to Edward Lord Dudley.

The 1959 Australian High Court judgement in the NRDC case[22] is particularly known for its articulation of patentable subject matter as:

The right question is: "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?" (at p269)

... the view which we think is correct in the present case is that the method the subject of the relevant claims has as its end result an artificial effect falling squarely within the true concept of what must be produced by a process if it is to be held patentable. This view is, we think, required by a sound understanding of the lines along which patent law has developed and necessarily must develop in a modern society. 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, ... And the significance of the product is economic; .

Furthermore, the NRDC decision is highly pertinent because of its discussion on discovery:

"The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion"

and

"There may indeed be a discovery without invention - ... because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end ...".

See Appendix 2 for further details.

3.2 The Bill

The Patent Amendment (Human Genes and Biological Materials) Bill 2010 proposes four amendments, as follows, with emphasis added:

1 Paragraph 18(1)(a)
Repeal the paragraph, substitute:
(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

2 Paragraph 18(1A)(a)
Repeal the paragraph, substitute:
(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

3 Subsection 18(2)
Repeal the subsection, substitute:
(2) The following are not patentable inventions:
(a) human beings, and the biological processes for their generation; and
(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

4 After subsection 18(4)
Insert:
(5) In this section:
biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.

4. Patentable Subject Matter internationally

4.1 Europe

Directive 98/44/EC of the European Parliament of 6 July 1998 on the legal protection of biotechnological inventions provides the following in Article 5:

```
 Article 5
1. The human body, at the various stages of its
formation and development, and the simple discovery of
one of its elements, including the sequence or partial
sequence of a gene, cannot constitute patentable
inventions.

2. An element isolated from the human body or
otherwise produced by means of a technical process,
including the sequence or partial sequence of a gene, may
constitute a patentable invention, even if the structure of
that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial
sequence of a gene must be disclosed in the patent
application.
```

4.2 Japan

The Examination Guidelines for Patent and Utility Model in Japan[23] (with added emphasis) state:

```
The first paragraph of Article 29(1) of the Patent Act reads:
          "Any person who has made an invention which is industrially applicable
may obtain a patent therefor ..."

 It has been long established in theory and practice to consider that the
above provision requires an invention to be "statutory" as well as "industrially
applicable." These Guidelines, in accordance with this established rule, explain
these two requirements, i.e., being "statutory" and "industrially applicable."

1. Statutory Inventions

 Article 2(1) of the Patent Act defines a statutory invention as a highly
advanced creation of technical ideas utilizing a law of nature. It should be
noted, however, that the term "highly" has been introduced in the definition to
differentiate "invention" from "device" under the Utility Model Act, and this
term is disregarded in judging whether an invention is statutory or not.

The following is a list of non-statutory inventions.

1.1 List of Non-statutory Inventions

 Since it is not a "creation of a technical idea utilizing a law of nature," any
one of the following is not considered to be a statutory invention.

(1) A law of nature as such
Since statutory inventions shall utilize a law of nature, a law of nature as
such, like a law of preservation of energy or a law of universal gravitation, is
not considered as a statutory invention.
```

(2) Mere discoveries and not creations
One of the requirements for a statutory invention is to be a "creation", and thus, mere discoveries, such as discoveries of natural things like an ore or natural phenomena, for which an inventor does not consciously create any technical idea, are not considered to be a statutory invention.
However, if things in nature such as chemical substances or microorganisms have been isolated artificially from their surroundings, then those are creations and considered to be a statutory invention.

4.3 South Korea

Article 2 of the Korean Patent Act[24] provides:

Definitions
The definitions of terms used in this Act are as follows:
(i) "invention" means the highly advanced creation of a technical idea using the law of nature;

The Korean Intellectual Property Office Examination guidelines[25] state (with emphasis added):

4.1 List of Non-statutory Inventions

The decision of whether an invention falls under the Patent Act Article 2 subparagraph (i) is not without challenge and the guidelines hereby exemplify the types of non-statuary inventions in order to help determine whether the invention is statutory.

...

4.1.2 Mere discoveries and not creations

A mere discovery is not deemed to be a creation because a discovery means to find out laws which exist in nature. A statutory invention requires to be a creation, and thus, mere discoveries, such as discoveries of natural things such as an ore or natural phenomena are not considered to be a statutory invention.

However, the method for artificially isolating substances from things in nature, not a mere discovery, is considered to be a statutory invention. So are the isolated chemical substances and microorganisms.

4.4 United States of America

In the US, patentable Subject Matter is defined in 35 U.S.C 101 which provides:

35 U.S.C. 101 Inventions patentable.

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.

In 28 June 2010, the US Supreme Court, decided Bilski *v.* Kappos[26] and reiterated three specific exemptions to patentability:

"laws of nature, physical phenomena, and abstract ideas."

We have some guidance from the case law as to examples of each of these exemptions. A "law of nature" includes E=mc2 and Newton's law of gravity. The business method of hedging financial risk as claimed in Bilski was held to be an "abstract idea".

4.5 The TRIPS Agreement.

Article 27 of the TRIPS Agreement[27] is as follows (with emphasis added):

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

5. Scope of the Senate Inquiry

The terms of reference were limited to the following compositions of matter and their derivatives:
(i) human and microbial genes and non-coding sequences; and
(ii) proteins.

By way of contrast, the only *subject matter* restriction of the Bill is "biological materials ... including DNA, RNA, proteins, cells and fluids".

6. Discussion

6.1 Current Australian Law on Patentable Subject-matter

The sole technological subject-matter restriction on patentability to be found in section 18 of the Act, is s.18(2):

```
 (2)  Human beings, and the biological processes for their generation, are not
patentable inventions.
```

Section 6 of the Statute of Monopolies provides for patents on any manner of new manufactures. The restrictions to patents found within s.6 are not technological subject matter restrictions. Both s.18 of Act and s.6 of the Statute are silent with respect to discoveries, natural phenomena, products of nature, and naturally occurring biological materials.

In sections 10-14, the Statute of Monopolies expressly permitted patents on saltpeter, alum, coal, wine, each of which could be at least one of a discovery, natural phenomenon, product of nature and a naturally occurring biological material. Furthermore, section 9 permitted exclusive rights for corporations without regard to subject matter.

In summary, we understand current Australian patent law to be the following:
(i) Patent eligible subject matter is "an artificially created state of affairs" of "economic significance"
(ii) The sole subject matter exclusion patentability is set out in s.18(2).
(iii) Judging an invention by use of the term "discovery" can be misleading;
(iv) A discovery could be patent-eligible if it suggests a practical application to a useful end; and
(v) Discovery which does not suggest a practical application to a useful end ("mere" discovery) is a discovery without invention.

6.3 The Bill, the Explanatory Memorandum and the Speech.

The first change contemplated by the Bill adds the word "full'. The effect of changing "within the meaning" to "within the full meaning" is unclear. One interpretation is that it draws in those parts of s.6 not currently part of the law. Would it mean that patents would be void unless they had a term of fourteen years? Would it mean that patents would be void unless they were awarded to directly inventors like the US system? If that is what is meant by "full" then it would involve a change in the law.

The second change adds the phrase "including the proviso", perhaps reflecting a concern that the "generally inconvenient" proviso is not currently law. In our opinion, while there may be doubt over *how* the "generally inconvenient" proviso may operate, *that* it operates seems less contentious[28]. It was one of the grounds of invalidity asserted in the Rescare[29] case.

The third and most substantial portion of the Bill is the third amendment. Its effect would be that without regard to whether they are isolated or purified and however made, and also without regard to whether they are novel, inventive or possessing utility, certain "biological materials" are unpatentable.

We think this is a subject matter exclusion to patentability. In other words, the Bill would mean that it would be irrelevant whether it was a discovery, a claim to a material could be found not eligible for a patent because of the subject matter of the claim.

But even if the Bill simply stated that discovery was not patentable, there would still be a difference between the Bill and current Australian law. In deciding invention, the Australian High Court cautions against reliance on the terms "discovery" and "work of nature". The High Court also made a distinction between potentially patentable discovery, and unpatentable mere discovery, a distinction which is not found in the Bill.

While it would be a question of fact, we think "isolation" *could* give rise to an "artificially created state of affairs" as defined in the NRDC decision, and would thus be patent eligible subject matter under current law, subject to all the other requirements of novelty, inventive step and utility.

The third amendment includes a test for identity or substantial identity. It is unclear to us how this test would be applied in practice. What makes a material a "biological" material? Does the test for "identical" require an inquiry into structural identity or functional identity? Does it require both functional and structural identity? How should a combination claim be treated which comprises a biological material as defined in the Bill and some other material?

The same issues apply to the question of whether a material is "substantially identical". How would analogues be treated under the Bill? If a material performed the same function as a biological material as defined in the Bill, would it be "substantially identical"? How would inversion, substitution or addition change the result?

Should the tests for "identical or substantially identical" be applied as a test for novelty and or inventive step?

Is it some form of equivalence test?
"having only insubstantial differences"[30]

or a functional equivalence test?
"if two ... [sequences] do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape."[31]

Such equivalence tests would seem to duplicate the inventive step provisions of the Act.

In appendix 3, we illustrate the uncertainty that would accompany the application of these tests for "identical or substantially identical" as proposed by the Bill.

6.3 International law

The European Directive on biotechnological inventions explicitly allows patents on isolated genes. Based on the Patent Examination guidelines of Japan and South Korea, patent law in those countries would also allow patents on the materials excluded by the Bill.

We speculate that under US law, the biological materials defined in the Bill would be considered a composition of matter, and thus would be statutory patent-eligible subject matter. As the Myriad case progresses through the US courts, the US position may become clearer.

The TRIPS Agreement requires that patents be available without discrimination as to the field of

technology, however Members may exclude from patentability inventions which meet the requirements of sections 2 or 3.

Section 2 permits exclusions where necessary to prevent commercial exploitation to protect *ordre public,* morality, human, animal or plant life or serious prejudice to the environment. We can contemplate that some biological materials, such as biological weapons, could cause serious harm to human health and society. But this does not mean all biological materials should be excluded from patentability. We suggest the way to include a patentability exclusion compatible with section 2 would be to define the exclusion by the words of section 2, or similar words, rather than by subject matter.

Since the exclusions to patentability defined in the Bill are not methods, section 3a is irrelevant. Section 3b relates to plants and animals other than microorganisms, and biological processes. We think the exclusions defined in the Bill would include materials which are outside those defined in section 3b.

6.4 Scope of inquiry

The amendments as proposed encompass a broader range of materials than were considered in the Senate inquiry.

The broader range explicitly includes cells and fluids, and it could also include carbohydrates, polysaccharides, and fats. This broader range of materials has applications beyond medical treatment.

One patent[32] relating to polysaccharides describes possible uses for the technology it discloses thus:

> Microbial polysaccharides are used for a broad variety of industrial applications including food production, chemical production (e.g., detergents, cosmetics, paints, pesticides, fertilizers, flocculants, film formers, lubricants and explosives), pharmaceutical production and waste treatment. In food production, microbial polysaccharides are commonly used as thickening, gelling and homogenizing agents. When added to a liquid, microbial biopolymers contribute to viscosity, emulsion stabilization, surface tension and adhesiveness. Thickening applications are particularly important in the production of solid and semi-solid food products including dairy and non-dairy foods such as yogurt, buttermilk, salad dressings, cheese, and ice-cream.

6.5 Licensing

The effective exclusive right given by a patent is the right, during the term of the patent, to authorise another person to exploit the invention[33]. The patent holder has the right to licence, or not to licence a third party. An unlicensed third party practising the invention as claimed may be sued for infringement.

In practice, human gene patent related litigation is rare, with one study finding about 0.4% of human gene patents being the subject of an infringement litigation[34], half of them in one lawsuit. But this does not mean that people do not fear being sued, even if it is uncommon.

If a patent holder chooses to licence a third party, licence fees may or may not be payable. A study[35] of 2,963 agreements reported in SEC filings estimates of the median costs of patent licences in the Medical and Pharma industries to be 5%. This is considerably less than the 400% discussed during the Senate Inquiry[36].

While a patent holder may decide not to licence a third party, that right not to licence does not stand in isolation. If a person is unable to obtain authorisation from a patent holder on reasonable terms and conditions, the reasonable requirements of the public are not being met, and the patent holder does not exploit the invention, the Act provides in section 133 that compulsory licences can be ordered. A compulsory licence may also be ordered if a patent holder contravenes the Competition and Consumer Act 2010.

Another form of licensing is the patent pool. In patent pools, different patent owners can bundle together rights as a package, and it has been suggested that the same may be possible in the biotechnology area[37]. A package of pooled licences to human gene patents could provide a one-stop shop for those seeking to work in the area. There is an analogy with copyright collection agencies.

7. Conclusions

1. What is current Australian law on the patentability of discoveries?
While Australian Patent law currently provides that *mere* discovery is unpatentable, a discovery could be patentable, if there is a suggestion of a practical application to a useful end, it meets all the other requirements of patentability such as novelty, inventive step, utility and it is an artificially created state of affairs as defined in the NRDC case.

2. Would the Bill change the law if enacted?
Since the Bill proposes a specific subject-matter exclusion to patentability, rather than for providing that "mere" discovery be unpatentable, we consider that enactment of the Bill would change Australian Patent law.

3. How would "identical or substantially identical" be tested in practice?
It is unclear how the test for identity or substantial identity should be conducted.

4. How does the Bill compare with International law?
We conclude that enactment of the Bill would give rise to inconsistencies between Australian law, and the laws of Europe, Japan, South Korea and the United States of America, and may not meet the requirements of the TRIPS agreement.

5. Should the Bill be enacted?
We do not doubt that a number of patients, medical practitioners and researchers have concerns about the patent system and about access to patented medical technologies.

While not a panacea, we think it may be possible to address those concerns through existing licensing provisions.

Whether or not it is discovery, *until* we know about it, the price of the next insulin is effectively infinite. However much funding is committed to medical research and development, it could always be argued that there should be more. If the patent system led to earlier discovery or brought extra funds for research, it has served a worthwhile purpose.

Differences between the laws of different countries are not merely curiosities. They can affect where money for research and development is directed, and where jobs lie. They can affect whether it is worthwhile for a business to supply product into a market. This means that the Bill could have an impact on the use of biological materials in medicines, and in a broad range of industrial and agricultural products.

For these reasons, we do not support enactment of the Bill as proposed.

The dilemma we face is how to bring about the widespread availability of new, low cost technologies. It involves a complex series of interactions between business, technology, society and law. It is something we must face with a sense of urgency and rational analysis. It is something which concerns us all.

APPENDIX 1

The Statute of Monopolies
proviso relating to corporations:

IX. Proviso for Charters of London and other Corporations. Provided alsoe, That this Act or any thing therein contayned shall not in any wise extend or be prejudicial unto the City of London, or to any Cittie Borough or Towne Corporate within this Realme, for or concerning any Graunts Charters or tres Patents to them or any of them made or granted, or for or concerning any Custome or Customes used by or within them or any of them, or unto any Corporacions Companies or Fellowshipps of any Art Trade Occupacion or Mistery, or to any Companies or Societies of Merchants within this Realme, erected for the mayntenance enlargement or ordering of any Trade of Merchandize, but that the same Charters Customes Corporacions Companies Fellowshipps and Societies, and their Liberties Priviledges Power and Immunities, shalbe and continue of such force and effect as they were before the making of this Act, and of none other; Any thing before in this Act contayned to the contrary in any wise notwithstanding.

Initially[38] there were further exceptions[39]

X. Provided also, and be it enacted that this act or any declaration, provision, disablement, penalty, forfeiture, or other thing before mentioned shall not extend to any letters patents or grants of privilege heretofore made or hereafter to be made of, for, or concerning printing: nor to any commission, grant, or letters patents heretofore made or hereafter to be made of, for, or concerning the digging, making, or compounding of saltpeter or gunpowder; or the casting or making of ordnance or shot for ordnance; nor to any grant of letters patents heretofore made, or hereafter to be made of any office or offices heretofore erected, made, or ordained, and now in being and put in execution, other than such offices as have been decreed by any his Majesty's proclamation or proclamations: but that all and every the same grants, commissions, and letters patents and all other matters and things tending to the maintaining, strengthening, or furtherance of the same or any of them, shall be and remain of the like force and effect, and no other, and as free from the declarations, provisions, penalties, and forfeitures contained in this act, as if this act had never been had nor made, and not otherwise.

XI. Provided also, and be it enacted that this act or any declaration, provision, disablement, penalty, forfeiture, or other thing before mentioned, shall not extend to any commission, grant, letters patents, or privileges, heretofore made or hereafter to be made of, for, or concerning the digging, compounding, or making of alum or alum-mines, but that all and every the same commissions, grants, letters patents, and privileges shall be and remain of the like force and effect, and no other, and as free from the declarations, provisions, penalties, and forfeitures contained in this act, as if this act had never been had nor made, and not otherwise.

XII. Provided also, and be it enacted that this act or any declaration, provision, penalty, forfeiture, or other thing before mentioned, shall not extend or be prejudicial to any use, custom, prescription, franchise, freedom, jurisdiction, immunity, liberty, or privilege heretofore claimed, used, or enjoyed by the governors and stewads and brethren of the fellowship of the Hostmen of the town of Newcastle-upon-Tyne, or by the ancient fellowship, guild,

or fraternity commonly called Hostmen; for or concerning the selling, carrying, lading, disposing, shipping, venting, or trading of or for any sea-coals, stone-coals or pit-coals forth or out of the haven and river of Tyne: or to a grant made by the said governors and stewards and brethren of the fellowship of the said hostmen to the late Queen Elizabeth, of any duty or sum of money to be paid for or in respect of any such coals as aforesaid; nor to any grants, letters patents, or commissions heretofore granted or hereafter to be granted of, for, or concerning the licensing of the keeping of any tavern or taverns, or selling, uttering, or retailing of wines to be drunk or spent in the mansion house or houses, or other place, in the tenure or occupation of the party or parties so selling or uttering the same; or for or concerning the making of any compositions for such licenses, so as the benefit of such compositions be reserved and applied to and for the use of his Majesty, his heirs, or successors, and not to the private use of any other person or persons.

XIII. Provided also, and be it enacted that this act or any declaration, provision, penalty, forfeiture, or other thing before mentioned shall not extend or be prejudicial to any grant or privilege for or concerning the making of glass by his Majesty's letters patents under the great seal of England, bearing date of the two and twentieth day of May in the one and twentieth year of his Majesty's reign of England, made and granted to Sir Robert Mansell, Knight, vice-admiral of England; nor to a grant or letters patents bearing date the twelfth day of June in the thirteenth of his Majesty's reign of England, made to James Maxwell, Esquire, concerning the transportation of calf-skins, but that the said several letters patents last mentioned shall be and remain of the like force and effect, and as free from the declarations, provisions, penalties, and forfeitures before mentioned as if this act had never been had nor made, and not otherwise.

XIV. Provided also, and be it declared and enacted that this act or any declaration, provision, penalty, forfeiture, or other thing before mentioned shall not extend or be prejudicial to a grant or privilege for or concerning the making of smalt by his Majesty's letters patents under the great seal of England bearing date the sixteenth day of February in the sixteenth year of his Majesty's reign of England, made or granted to Abraham Baker; nor to a grant of privilege for or concerning the melting of iron ore and of making the same into cast works or bars with sea-coals or pit-coals by his Majesty's letters patents under the great seal of England bearing date the twentieth day of February in the nineteenth year of his Majesty's reign of England, made or granted to Edward Lord Dudley, but that the same several letters patents and grants shall be made and remain of the like force and effect and as free from the declarations, provisions, penalties, and forfeitures before mentioned as if this act had never been had nor made, and not otherwise.

APPENDIX 2

Excerpt from NRCD decision:

... "It only confuses the issue," the learned Justice said, "to introduce such terms as 'the work of nature' and the 'laws of nature'. For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature', and any patentable composite exemplifies in its properties 'the laws of nature'. Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost any patent". (1948) 333 US, at pp 134, 135 (92 Law Ed, at p 591) The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. There may indeed be a discovery without invention - either because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of "manufacture". But where a person finds out that a useful result may be produced by doing something which has not been done by that procedure before, his claim for a patent is not validly answered by telling him that although there was ingenuity in his discovery that the materials used in the process would produce the useful result no ingenuity was involved in showing how the discovery, once it had been made, might be applied. The fallacy lies in dividing up the process that he puts forward as his invention. It is the whole process that must be considered; and he need not show more than one inventive step in the advance which he has made beyond the prior limits of the relevant art. This is perhaps nowhere more clearly put than it was by Fletcher Moulton L.J. in Hickton's Patent Syndicate v. Patents and Machine Improvements Co. Ltd. (1909) 26 RPC 339 when he said of Watt's invention for the condensation of steam, out of which the steam engine grew: "Now can it be suggested that it required any invention whatever to carry out that idea when once you had got it? It could be done in a thousand ways and by any competent engineer, but the invention was in the idea, and when he had once got that idea, the carrying out of it was perfectly easy. To say that the conception may be meritorious and may involve invention and may be new and original, and simply because when you have once got the idea it is easy to carry it out, that that deprives it of the title of being a new invention according to our patent law, is, I think, an extremely dangerous principle and justified neither by reason nor authority" (1909) 26 RPC, at pp 347-348 (at p264)

14. ... The inquiry which the definition demands is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the section. It is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose of the Statute of Monopolies. One may remark that although the Statute spoke of the inventor it nowhere spoke of the invention; all that is nowadays understood by the latter word as used in patent law it comprehended in "new manufactures". The word "manufacture" finds a place in the present Act, not as a word intended to reduce a question of patentability to a question of verbal interpretation, but simply as the general title found in the Statute of Monopolies for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed. It is therefore a mistake, and a mistake likely to lead to an incorrect conclusion, to treat the question whether a given process or product is within the definition as if that question could be restated in the form: "Is this a manner (or kind) of manufacture?" It is a mistake which tends to limit one's thinking by reference to the idea of making tangible goods by hand or by machine, because "manufacture" as a word of everyday speech generally conveys that idea. The right question is: "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?" (at p269)

25. Notwithstanding the tendency of these decisions, the view which we think is correct in the present case is that the method the subject of the relevant claims has as its end result an artificial effect falling squarely within the true concept of what must be produced by a process if it is to be held patentable. This view is, we think, required by a sound understanding of the lines along which patent law has developed and necessarily must develop in a modern society. 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, ... And the significance of the product is economic; ... Recognition that the relevance of the process is to this economic activity old as it is, need not be inhibited by any fear of inconsistency with the claim to novelty which the specification plainly makes. The method cannot be classed as a variant of ancient procedures. It is additional to the cultivation. 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. (at p277)

Excerpt from Bilski *v.* Kappos[40]

Section 101 thus specifies four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter. "In choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." Diamond v. Chakrabarty, 447 U. S. 303, 308 (1980). Congress took this permissive approach to patent eligibility to ensure that "'ingenuity should receive a liberal encouragement.'" Id., at 308–309 (quoting 5 Writings of Thomas Jefferson 75–76 (H. Washington ed. 1871)).

The Court's precedents provide three specific exceptions to §101's broad patent-eligibility principles: "laws of nature, physical phenomena, and abstract ideas." Chakrabarty, supra, at 309. While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be "new and useful." And, in any case, these exceptions have defined the reach of the statute as a matter of statutory stare decisis going back 150 years. See Le Roy v. Tatham, 14 How. 156, 174–175 (1853). The concepts covered by these exceptions are "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none." Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U. S. 127, 130 (1948).

The §101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy "the conditions and requirements of this title." §101. Those requirements include that the invention be

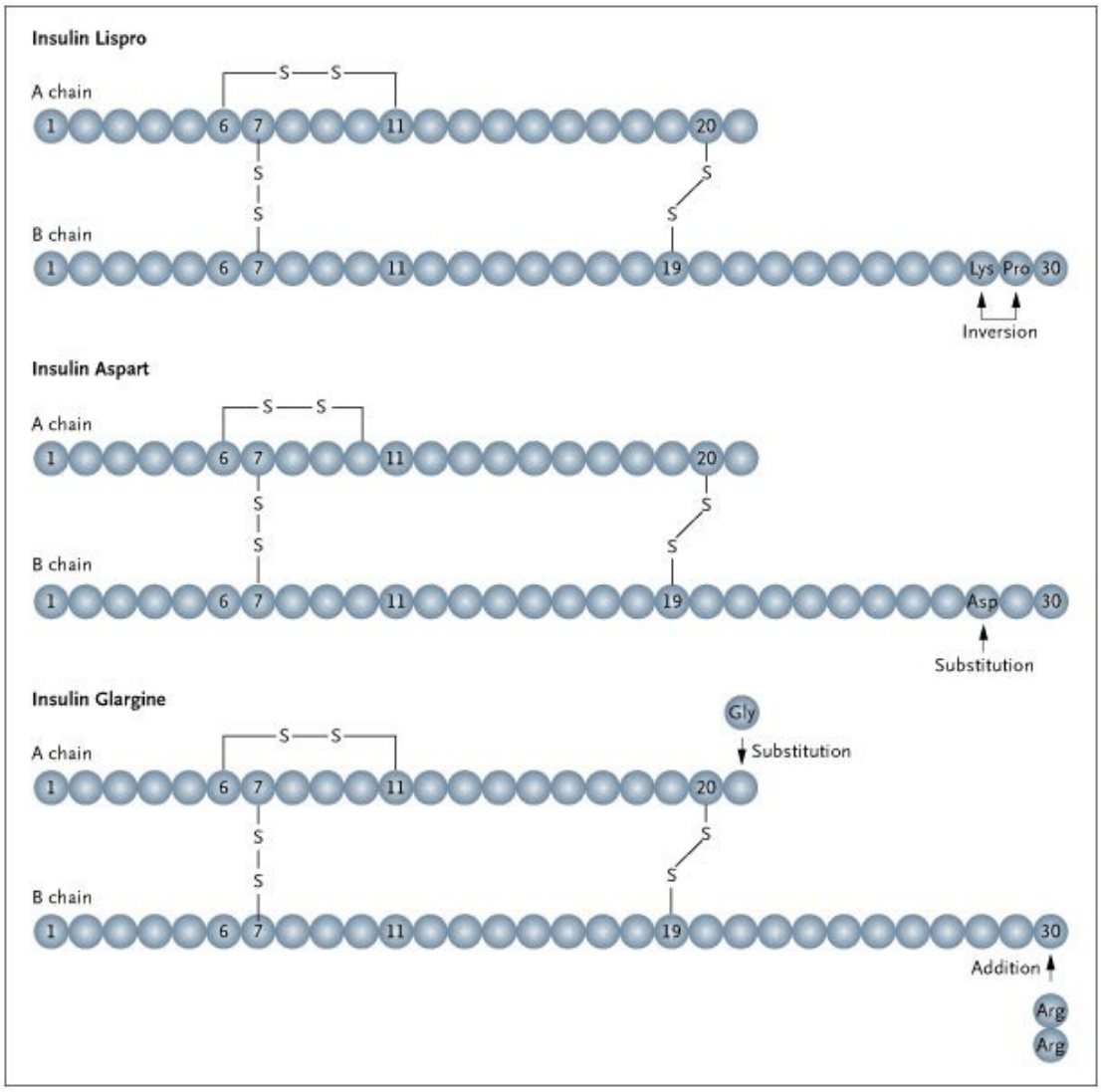
novel, see §102, nonobvious, see §103, and fully and particularly described, see §112.

APPENDIX 3 - Practical Examples

EXAMPLE 1: Insulin analogues

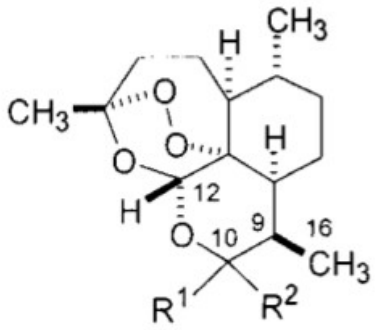
A number of insulin analogues have been developed including insulins lispro, aspart and glargine. See Hirsch[41], and figure reproduced below. They differ from "native" insulin by at least one of inversion, substitution and addition. It is unclear whether these analogues would be considered "identical or substantially identical" for the purpose of the Bill.

Figure reproduced from Hirsh[42]



EXAMPLE 2: Artemisinin

Artemisinin[43], a sesquiterpene lactone endoperoxide extracted from *Artemisia annua* L, is highly effective against multi-drug-resistant *Plasmodium* spp., but is in short supply and unaffordable to most malaria sufferers[44]. A variety of derivatives are known, see the following figure from Ekthawatchai et al. (2001)[45].



1 (artemisinin)	$R^1 = R^2 = O$
2 (artemether)	$R^1 = H$, $R^2 = OMe$
3 (arteether)	$R^1 = H$, $R^2 = OEt$
4 (sodium artesunate)	$R^1 = H$, $R^2 = OOCCH_2CH_2COONa$
5 (sodium artelinate)	$R^1 = H$, $R^2 = OCH_2$–C$_6$H$_4$–COONa

Would Artemether[46] be considered "substantially identical" to Artemisinin under the Bill?

Artemisinin analogs are the subject of Australian Patent AU 768872 B2[47], filed by applicants Hauser, Inc. and Johns Hopkins University. How would one judge whether the claims of this patent would fall within the subject-matter excluded by the Bill?

EXAMPLE 3: Polysaccharides

The polysaccharides are a broad class of carbohydrate polymers with a wide variety of uses, such as thickeners and food additives. Many are of plant or bacterial origin.

Australian Patent AU 2002358351 B2 is entitled "Negatively charged polysaccharide derivable from Aloe vera". It is part of a family of patents and patent applications related to PCT Application publication WO 2003/055918, and including European Patent EP 1461361 B1, and US Patent Publication US 2005/0019433 A1. While the US Patent application is currently rejected under 35 U.S.C. §103 for lack of inventive step, it is not under rejection for failing to meet 35 U.S.C. §101, inventions patentable.

Claim 1 of the AU patent is:

1. A composition of matter in isolated form comprising polysaccharides derivable from Aloe vera with the following characteristics:
a) the polysaccharides comprise 60-100 % D-mannose, 40-0 % D-glucose and 0-10 % other monosaccharides
b) the polysaccharides are negatively charged
c) the polysaccharides bind to a positively charged column
d) the average molecular weight is higher than 50 kD.

Australian Patent 2001 239737 B2 relates to biopolymers which may be used to thicken liquids including liquid foods, as well as an additive to pharmaceuticals, beauty products and coating agents.

Claims 1-3 are:

1. An isolated plasmid of approximately 20 kb which is derived from *Lactococcus lactis* subspecies *cremoris* Ropy 352, wherein the plasmid, when expressed in the transformed laboratory strain of *Lactococcus* MG1363, controls expression of a ropy polysaccharide, in which the polysaccharide has the following characteristics:

Composition: Glucose: range of 54% to 58%
Galactose: range of 42% to 46%
Charged: Yes
Molecular weight: range of 800,000 to 8,000,000
Phosphorus: Present in backbone or sidechain
Structure: endpoints: galactose;
branchpoints: glucose.

2. An isolated plasmid according to claim 1, wherein said plasmid is isolated from *Lactococcus lactis* subspecies *cremoris* Ropy 352 as deposited with the USDA-ARS-NCAUR-NRRL as deposit accession number NRRL B-30229.

3. A purified ropy polysaccharide when expressed by a cell comprising a plasmid according to claim 1 or claim 2, wherein said polysaccharide has the following characteristics:

Composition: Glucose: range of 54% to 58%
Galactose: range of 42% to 46%
Charged: Yes

```
Molecular weight: range of 800,000 to 8,000,000
Phosphorus: Present in backbone or sidechain
Structure:  endpoints: galactose;
            branchpoints: glucose.
```

Would either of these patents have to be revoked should the Bill pass?

EXAMPLE 4: Chlorotoxin

Chlorotoxin is a small peptide that was originally isolated from the venom of a scorpion, *Leiurus quinquestriatus*. It has the remarkable property of specifically binding to gliomas, a form of brain tumors in humans[48].

Chemically synthesized chlorotoxin is named TM601 to distinguish it from the naturally occurring peptide[49]. Would TM601 be patent eligible subject matter should the Bill become law?

Laying aside issues of inventive-step, would TM601 conjugated to a radioisotope such as 131-iodine be patent eligible should the Bill become law?

If TM601 by itself was not patentable, would a claim to a combination of TM601 and bevacizumab be patent eligible should the Bill become law?[50]

EXAMPLE 5: Human Genes

Myriad is a spin-off company from the Centre for Cancer Genetics Epidemiology at the University of Utah. The background to the US Myriad gene case has been discussed at length by others[51],[52],[53],[54]. There are several patents involved. One is US Patent 5,747,282 which stems from a patent application filed 12 August 1994 and relates to the BRCA1 gene. On the face of the patent, the assignees are Myriad Genetics, Inc.; the University of Utah Research Foundation; and the United States of America as represented by the Secretary of Health and Human Services.

Claim 2 of US 5,747,282 is:

2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.

In the 2nd reading Speech for the Bill, the Senator remarked:

More recently the US Department of Justice has filed an amicus brief (friend-of-the-court) in the appeal in that case stating that the "longstanding policy" which had been applied by the United States Patent Office over the grant of such patents was contrary to US patent law.

However, the US Department of Justice Amicus brief identifies claim 2 as being directed towards complementary DNA (cDNA)[55], and takes the position that such claims *are* patent-eligible subject matter, stating:

...the district court erroneously cast doubt on the patent-eligibility of a broad range of man- made compositions of matter whose value derives from the information- encoding capacity of DNA. Such compositions — e.g., cDNAs, vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops, created with the aid of such molecules — are in every meaningful sense the fruits of human ingenuity and thus qualify as "'human-made inventions'" eligible for patent protection under section 101.

It is unclear whether under the Bill, cDNA would be patent-eligible. Is it the information-encoding capacity by which one judges identity or substantial identity? Given that an isolated sequence may be only a few thousand base pairs, how does one make a comparison with a chromosome which is much larger?

1 Angus Maddison, *The World Economy,* OECD Publishing, 2001, 31-37.
2 Matthew Fisher, *Fundamentals of Patent Law* (Oxford and Portland, Oregon: Hart Publishing), 2007, 25-27.
3 CJ Rutty, Couldn't live without it: Diabetes, the Costs of Innovation and the Price of Insulin in Canada, 1922-1984, CBMH/BCHM/ Volume 25:2 2008 / p. 407-431
4 Nobel Prize in Physiology or Medicine 1923 <http://nobelprize.org/nobel_prizes/medicine/laureates/1923/banting-bio.html>
5 Frederick Banting, Wikipedia entry, accessed 4 February 2011 <http://en.wikipedia.org/wiki/Frederick_Banting>
6 Banting Postdoctoral Fellowships, Government of Canada, Assessed 7 February 2011, <http://banting.fellowships-bourses.gc.ca/about-a_propos/banting-eng.html>
7 CJ Rutty, Couldn't live without it: Diabetes, the Costs of Innovation and the Price of Insulin in Canada, 1922-1984, CBMH/BCHM/ Volume 25:2 2008 / p. 423-424.
8 *ibid.*
9 *ibid*
10 The Nobel Prize in Physiology or Medicine 1945 <http://nobelprize.org/nobel_prizes/medicine/laureates/1945/florey-bio.html> assessed 17 February 2011.
11 Aside from making a decision not to file patents, it may also not have been possible in the UK at the time. See Lai, "*Penicillins: Their Chemical History and Legal Disputes in New Zealand" Chemistry in New Zealand* (2009): 116-124
12 For example, US Patent 2,423,873 (Cohill and Moyer), *"Method for Production of Increased Yields of Penicillin"*
13 Bud, *"Penicillin and the new Elizabethans" British Journal for the History of Science* (1998) 31:305-333.
14 Abraham, "*A Glimpse of the Early History of the Cephalosporins*", *Reviews of Infectious Diseases* 1:99-105
15 Lowe, "*Obituary: Sir Edward Abraham*", The Independent, 13 May 1999, <http://www.independent.co.uk/arts-entertainment/obituary-sir-edward-abraham-1093226.html> assessed 19 February 2011.
16 Senator HEFFERNAN, Transcript of ABC TV Four Corners from 6 September 2010, Accessed 3 February 2010 <http://www.abc.net.au/4corners/content/2010/s3004027.htm>
17 Sen. Bill HEFFERNAN, 24 November 2010, Speech to the Australian Senate ('the Speech').
18 Senator HEFFERNAN, Transcript of Commonwealth of Australia Senate Community Affairs Reference Committee, 4 August 2009. Accessed 3 February 2011 <http://www.aph.gov.au/hansard/senate/commttee/S12301.pdf>
19 Statute of Monopolies 1623, UK National Archives, Office of Public Sector Information, assessed 12 January 2011, <http://www.statutelaw.gov.uk/content.aspx?activeTextDocId=1518308>
20 Potassium nitrate. See http://en.wikipedia.org/wiki/Potassium_nitrate
21 Potassium alum. See http://en.wikipedia.org/wiki/Potassium_alum
22 National Research Development Corporation v Commissioner of Patents, (1959) 102 CLR 252, (1961) RPC 134, 1A IPR 63
23 Chapter 1, Accessed 2 February 2011, <http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm>
24 Accessed 2 February 2011 <http://www.kipo.go.kr/upload/en/download/PatentAct.pdf.>
25 Accessed 2 February 2011 <http://www.kipo.go.kr/upload/en/download/RequirementsforPatentability.pdf>
26 561 U.S. (2010)
27 Agreement on Trade-Related Aspects of Intellectual Property Rights, World Trade Organisation, Assessed 30 January 2011 <http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5>
28 In *Welcome Real-Time SA v Catuity* [2001] FCA 445 (17 May 2001) [131-132] Herrey J stated:

> The respondents argued that the Patent was, within the meaning of the Statute of Monopolies, generally inconvenient as it placed a restraint on traders in developing and operating loyalty and incentive schemes which were "a commonplace way of doing business and had been so for many years in both the real and on line worlds". It was said that the applicant was seeking to monopolise a series of known integers for the purpose of a particular kind of loyalty scheme and was thereby preventing other traders from seeking to use those integers or the same composition of them in their own customer loyalty schemes.
>
> But if an invention otherwise satisfies the requirement of s 18 it can hardly be a complaint that others in the relevant field will be restricted in their trade because they cannot lawfully infringe the patent. The whole purpose of patent law is the granting of monopoly.

We note the remarks in the ACIP report on Patentable Subject Matter, December 2010, on page 52, in respect of the judgement by Heerey J, nevertheless, we do not read into the judgement a repudiation of "generally inconvenient" as a separate ground of rejection. Instead we understand the judgement to mean only that a grant of a monopoly is not in of itself generally inconvenient.

29 Anaesthetic Supplies Pty Limited v Rescare Limited [1994] FCA 1065; (1994) 122 ALR 141 (1994) Aipc 91-076 (5 May 1994)
30 Warner-Jenkinson Company, Incorporated, et al. v. Hilton Davis ChemicalCompany 520 U.S. 17
31 Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605 (1950)

32 Australian Patent AU 2001/239737 B2
33 The definition of *exploit* in Schedule 1 of the Act would appear to give a patent owner the right to make, hire, sell or otherwise dispose of a product of their invention. In practice, a patent owner does not have that right if they would infringe the patent of another.
34 Eighteen from a set of 4,270. Holman, Christopher M., "*The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation"*. UMKC Law Review (2007) 76: 295. Available at SSRN: http://ssrn.com/abstract=1090562
35 Varner TR "*Technology Royalty Rates in SEC Filings*", Licensing Executive Society magazine, Les Nouvelles, September 2010:120-127.
36 Senator HEFFERNAN, Transcript of Commonwealth of Australia Senate Community Affairs Reference Committee, Monday 3 August 2009, page CA32. Accessed 23 February 2011 <http://www.aph.gov.au/hansard/senate/commttee/S12301.pdf>
37 Clark *et al.*, Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?, United Stated Patent and Trademark Office, 5 December 2000.
38 Ss. 10-12 were repealed by Patents, Designs and Trade Marks Act 1883, see schedule 3. Ss. 13, 14 were repealed by Statute Law Revision Act 1948.
39 William Hyde Price, The English Patents of Monopoly (Cambridge, MA., Harvard University Press,1913), 8; Accessed 26 January 2011, <www.questia.com>, Appendix A.
40 561 U.S. (2010)
41 Hirsch, Insulin Analogues, N Engl J Med 2005; 352:174-183
42 Hirsch, *op. cit.*
43 http://en.wikipedia.org/wiki/Artemisinin
44 Nature, Vol 440, 13April 2006, doi:10.1038/nature04640
45 Ekthawatchai et al. C-16 Artemisinin derivatives and their antimalarial and cytotoxic activities, J. Med. Chem 2001, 44, 4688-4695.
46 http://en.wikipedia.org/wiki/Artemether
47 Artemisinin analogs having antimalarial, antiproliferative, and antitumor activities and chemoselective methods of making the same.
48 Deshane J, et al., Chlorotoxin Inhibits Glioma Cell Invasion via Matrix Metalloproteinase-2, J Biol. Chemistry, 2003, 278: 4135.
49 Jacoby DB, et al, Potent Pleiotropic Anti-angiogenic Effects of TM601, a Synthetic Chlorotoxin Peptide, Anticancer research, 2010, 30: 39-46.
50 Jacoby et al., "*Potent Pleiotropic Anti-angiogenic Effects of TM601, a Synthetic Chlorotoxin Peptide*", AntiCancer Research (2010) 30:39-46.
51 Williams-Jones, B. 2002. “History of a Gene Patent: Tracing the Development, Marketing, and Application of Commercial BRCA Testing in Canada" Health Law Journal 10: 121-144.
52 Myriad Genetics, Inc., Appeal From the United State District Court For the Southern District of New York, Assessed 6 February 2011, <http://patentdocs.typepad.com/files/myriad-brief-of-appellant.pdf>
53 U.S. Department of Justice, Brief for the United States as Amicus Curiae in Support of Neither Party, New York Times, accessed 6 February 2011, <http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf>
54 American Intellectual Property Law Association, Brief for Amicus Curie in Support of Reversal, But in Support of Neither Party, Assessed 6 February 2011, <http://patentdocs.typepad.com/files/aipla-amicus-brief.pdf>
55 a DNA molecule that is complementary to a specific messenger RNA, cDNA. Dictionary.com. Dictionary.com Unabridged. Random House, Inc. http://dictionary.reference.com/browse/cDNA (accessed: February 05, 2011).