

LORD COOKE AND PATENTS: THE SCOPE OF "INVENTION"

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What inventions are patentable is the core issue in patent law. Lord Cooke, when he was a Court of Appeal judge, ruled that the definition of invention, under the Patents Act 1953, included the part of the Statute of Monopolies of 1623 known as the proviso. Amongst other things the proviso excludes matters that raise prices of commodities at home or are generally inconvenient from being inventions for the purposes of the Act. Cooke J held that the presence of the proviso meant that when patents are applied for inventions that raise matters of economic concern the courts should resist breaking new ground and Parliament should deal with the matter. In reaching that interpretation of the definition of invention Cooke J said that because of the diversity of international views on the patentability of methods of medical treatment, the Court could not shut its eyes to the fact that the application before it might result in raising prices of commodities at home or be generally inconvenient. At the core of Cooke J's reasoning was the particular economic questions that arise for a country the size of New Zealand. This article discusses the treatment of Cooke J's approach in the courts and in the patent registration system. The article also discusses the role of public opinion concerning economic and social policy issues arising in the patent system. The article concludes that Cooke J's interpretation should continue to guide New Zealand's approach to what is an invention, and thus what is patentable subject matter.

I INTRODUCTION

Lord Cooke was not an intellectual property law specialist, but he heard several cases in the field. Some of his intellectual property decisions had a significant impact on the law and continue to affect the way it develops. An example is *Klissers v Farmhouse Bakeries*.¹ That decision discussed the factors a plaintiff must establish to obtain an interim injunction, in particular, whether there is a serious question to be tried and the balance of convenience. In *Klissers* Cooke J held that those "two heads are not exhaustive" and "marshalling considerations under them is an aid to determining, as regards the grant or refusal of an interim injunction, where overall justice lies".² *Klissers* was a

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1 *Klissers v Farmhouse Bakeries* [1985] 2 NZLR 129,140-142 Cooke J.

2 *Ibid*, 142 Cooke J.

passing off case. However, its consideration of the relationship between whether there is a serious question to be tried and balance of convenience are central to interlocutory injunctions in all areas of intellectual property and is particularly important where the grant of an interlocutory injunction often determines the whole matter.³

This article discusses a case which significantly contributed to patent law. Cooke J's judgment in *Wellcome v Commissioner of Patents*⁴ was an important development in determining what is patentable subject matter. The Court of Appeal held that methods of medical treatment were not an invention and therefore not patentable subject matter. Part II of this article explains the *Wellcome* decision and Cooke J's reasoning. It outlines his discussion of the definition of invention and its function in relation to the scope of patentable subject matter. Cooke J concluded that the part of the definition of invention, which excludes matters of general inconvenience, was how the legislature had intended that major steps in finding new subject matters patentable should be left to Parliament.⁵ Leaving matters to Parliament was a marked contrast to his more renowned approach of being prepared to reach conclusions on issues that Parliament has left open because he interpreted that Parliament's intention was that there be judicial interpretation.⁶ He did not believe that such an intention existed in patent law. One important reason for this was Parliament's ability to consider a wider range of relevant perspectives than is possible in the adversarial process.⁷

Subsequent to *Wellcome* Gault J in *Pharmac v Commissioner of Patents* doubted Cooke J's view of the definition of invention,⁸ in part because of his view of international obligations relating to patent law. Part III discusses the main international treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),⁹ and explains why it supports Cooke J's view on the definition of invention. Part IV discusses the importance of a well defined patent system and some aspects of proposed patent law reform regarding potential exclusions from the scope of patentability. Part V discusses the economic and social policy issues that may arise in assessing what is an invention and consequently what is patentable subject matter. This leads to the discussion in Part VI regarding policy choices about the subject matter of invention and the role of the courts,

3 Ibid.

4 *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA) [*Wellcome*]. The judges were Cooke, McMullin and Somers JJ. My focus here is on the judgment of Cooke J, although Somers J and McMullin J, in particular, agreed with his approach to the role of Parliament and the role of the courts in the patenting process.

5 *Wellcome*, above n 4, 391 Cooke J.

6 An example of this approach is *New Zealand Maori Council v Attorney-General* [1987] 1 NZLR 641.

7 *Wellcome*, above n 4, 391 Cooke J.

8 *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529 [*Pharmac*].

9 Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) 33 ILM 81, see the preamble and articles 27:2 and 27:3.

Parliament and public opinion in those choices. Part VII discusses recent developments at the Intellectual Property Office of New Zealand ("IPONZ") on patentable subject matter and the definition of invention. IPONZ is not following Cooke J's approach. I conclude that because of the economic significance of patents and the justifications for their grant the New Zealand patent registration system must engage more fully with economic and social policy considerations. The current patent registration system makes this hard. Cooke J pointed out that it is also difficult in the adversarial system. Parliament has also not fully assessed and weighed many economic and social policy concerns. Cooke J in *Wellcome* established several reasons why economic issues cannot be divorced from patents. This article concludes that the failure of any stage of the patenting process to deal with economic and social policy concerns is an unsound path for New Zealand to follow. It does not foster confidence that the system is for New Zealand's economic benefit.

II WELLCOME'S CONTRIBUTION TO PATENT LAW

Wellcome was a landmark decision. It was the first appellate decision about the patentability of "a method of treatment of disease or illness in human beings".¹⁰ The application was effectively one to patent a new use of a combination of known pharmaceutical substances. The Wellcome Foundation applied for a patent for a method of treating or preventing meningeal leukaemia with substances that had been used for treating malaria.¹¹ The Patent Office refused to accept the application primarily because it "did not relate to a manner of new manufacture as defined in the Patents Act 1952, s 2 [definition of invention] as interpreted over the years".¹² In the Supreme Court Davison CJ reversed the Patent Office decision, holding that a patent may be obtained for a process for the medical treatment of humans.¹³ He adopted the "test as posed by the High Court of Australia in *NRDC*",¹⁴ which was:¹⁵

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?

NRDC involved an application for a new use of known chemicals as a herbicide. The High Court of Australia held this was patentable because the combination of the chemicals in the particular way and as a herbicide involved the necessary novelty. In *Wellcome* Davison CJ concluded that the new use of known substances was by analogy a manner of new manufacture. He concluded the Patents Act did not prohibit registering a method of medical treatment despite there

10 *Wellcome*, above n 4, 386 Cooke J.

11 *Ibid.*

12 *Ibid.*

13 *Wellcome v Commissioner of Patents* [1979] 2 NZLR 591 (SC).

14 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

15 *Wellcome*, above n 13, 617.

being a long history that methods of medical treatment were not patentable.¹⁶ The Commissioner of Patents appealed. The appeal necessarily involved interpreting the definition of invention. That definition incorporates the Statute of Monopolies of 1623. This declared monopolies void except as provided for in section 6:¹⁷

Provided, also, and be it declared and enacted, that any declaration before mentioned shall not extend to any letter patents and grants of privilege for the term of 14 years or under, hereafter to be made, of the sole working or making of any new manner of manufactures within this Realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use, so as also they be not contrary to the law, nor mischievous to the State, by raising prices at home, or hurt of trade, or generally inconvenient. ...

The concepts of raising prices at home, hurt of trade or generally inconvenient qualify permitted inventions under the section and are often referred to as "the proviso". In *Wellcome Cooke J* observed that:¹⁸

...we cannot realistically shut our eyes to the possibility that in the language of the Statute of Monopolies the change sought by the respondent might result in "raising prices at home" or be "generally inconvenient".

Therefore Cooke J held that the Court should not, rather Parliament should, decide whether or not methods of medical treatment were patentable. Cooke J reasoned that because of economic considerations for a country the size and type of New Zealand, any extension of patent law, of the kind the applicant suggested, was a matter for Parliament, because Parliament has the ability to seek specialist advice and consider any opposing views.¹⁹ Cooke J recognised that *NRDC* had developed the law, but he did not consider it was the appropriate authority to follow for methods of medical treatment. Cooke J held that a rule that "a discovery for a new use of a known product cannot provide a basis for grant must, in its bald form, be rejected as outmoded."²⁰ Nonetheless Cooke J refused to extend *NRDC* to allow patentability of new uses of known substances in the field of methods of medical treatment, holding:²¹

...there remains, I respectfully think, a deep-seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong in the area of economic endeavour or trade and commerce.

16 Courts have given different reasons for this ground, see *Wellcome*, above n 4 and *Upjohn Company's (Robert's) Application* [1977] RPC 94.

17 Patents Act 1953, s 2.

18 *Wellcome*, above n 4, 391 Cooke J.

19 *Ibid*.

20 *Ibid*, 388 Cooke J.

21 *Ibid*.

He then considered the approaches to this area of patent law internationally. He concluded that the issue was not easily resolved because of differing approaches internationally. In his view, while the definition of invention is flexible enough to accommodate new technologies as they develop, the Statute of Monopolies proviso means that the definition is not unlimited. The case indicated those limits. The Statute of Monopolies proviso means that with technological developments, which raise matters of raising prices at home or general inconvenience, and for which there is no international consensus on patentability, it is the role of Parliament to indicate whether such developments come within the definition of invention, not the role of the courts. Although *Wellcome* concerned methods of medical treatment, Cooke J's analysis applies to other potential subject matter of patent law.

The concepts of raising prices at home and generally inconvenient in the 21st century are matters of economic and social policy.²² Cooke J's interpretation leaves the question of whether, absent the Statute of Monopolies, matters of economic concern and social policy should be relevant to the patent registration system. The alternative is that the definition of invention catches any subject-matter regardless of its economic or social policy implications.²³ The undesirability of this alternative is discussed further below.

Since *Wellcome*, New Zealand law has developed on the issues of the patentability of new uses of known pharmaceuticals and methods of medical treatment.²⁴ The Court of Appeal in *Pharmac*²⁵ held that such new uses, known by then as "Swiss claims", were patentable.²⁶ The patent claim in *Wellcome* was not framed as a Swiss claim as that terminology was not commonly used "pharmaceutical patent speak" until a few years after the decision. However, the claim could have been framed as a Swiss claim because a Swiss claim is a claim to patentability of a new use of a known pharmaceutical substance and that was what the Wellcome Foundation applied to patent.²⁷ Although, at the time of *Wellcome*, such claims were not patentable.²⁸

22 Although a focus on price might raise concerns that such a basis for exclusion from patentability is of a trade discriminatory nature, see discussion below in Part III.

23 Once the invention is defined it is then measured against the criteria of patentability; novelty, obviousness and utility.

24 *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 (CA) [*Pfizer*].

25 *Pharmac*, above n 8.

26 *Ibid*, para 17 Gault J for the Court. In such a claim the novelty is found in the use, rather than the novelty of the substance or method of making it. The original Swiss claim was granted in Switzerland. For a discussion of the origins of Swiss claim patents, see Daniel Armstrong "The Arguments of Law, Policy and Practice Against Swiss-Type Patent Claims" (2001) 32 VUWLR 201.

27 *Pharmac*, *ibid*, para 3. Gault J for the Court describes a Swiss claim as "the use, in the manufacture of a medicament, of [*the active compound*] as an active ingredient in a [*the newly invented activity*] composition in admixture with an inert carrier."

28 *Wellcome*, above n 4, 391 Cooke J.

Gault J in *Pharmac* went to some lengths to explain that, in concluding that Swiss claim applications were patentable, he was not overruling *Wellcome*.²⁹ In particular, Gault J emphasised that the principle that patents should not be granted for methods of medical treatment remained undisturbed.³⁰ He reasoned that despite the prohibition on methods of medical treatment being patentable, Swiss claim applications were now patentable. In essence, the ruling in *Pharmac* could be interpreted as suggesting that patents in the Swiss claim form for new uses of known pharmaceutical substances are not methods of medical treatment. Therefore Gault J held that the *Wellcome* exclusion did not apply.

Gault J disagreed with *Wellcome* and suggested that there was doubt whether the Statute of Monopolies proviso was part of the definition of invention.³¹ Gault J's concern appeared to have been the compatibility of the proviso with the TRIPS Agreement.³² The TRIPS Agreement permits the exclusion of methods of medical treatment from patentability³³ and other exclusions also.³⁴ Thus Gault J's interpretation of the TRIPS Agreement was wrong.³⁵

Subsequent to *Pharmac* the Court of Appeal in *Pfizer*³⁶ upheld the rule that methods of medical treatment are not patentable. Counsel for Pfizer Ltd submitted that *Pharmac* had overruled *Wellcome*.³⁷ The Court of Appeal did not accept this and regarded *Pharmac* as limited to Swiss claims.³⁸ *Pfizer* discussed the reasoning in *Wellcome*. O'Regan J summarised Cooke J's interpretation of the definition of invention as "the resolution of the issue as a balancing exercise, with the national economic interest at its heart".³⁹ The Court also agreed with *Wellcome* in finding that the Statute of Monopolies proviso formed part of the definition of invention.⁴⁰ In *Pfizer*, Hammond J was particularly concerned to emphasise the public interest in interpreting the scope of the definition of invention. He noted that "exceptions" to patentability developed in patent law are

29 A point that the headnote writer did not seem to have appreciated. See *Pharmac*, above n 8, 529.

30 *Ibid*, para 39 Gault J for the Court.

31 *Ibid*, para 20 Gault J for the Court. That the Statute of Monopolies is not part of the definition was also unsuccessfully argued in *Pfizer*, above n 24.

32 *Pharmac*, above n 8, paras 64-65 Gault J for the Court.

33 TRIPS Agreement, above n 9, art 27:2.

34 See Part III.

35 See TRIPS Agreement, above n 9.

36 The judgments in that decision were given by Anderson P, O'Regan J on behalf of Glazebrook, William Young and O'Regan JJ, and Hammond J, who gave a separate, although concurring judgment.

37 *Pfizer*, above n 24, paras 35-37 O'Regan J (Glazebrook and William Young J concurring).

38 *Ibid*, paras 59-60 O'Regan J (Glazebrook and William Young J concurring).

39 *Ibid*, para 24 O'Regan J (Glazebrook and William Young J concurring).

40 *Ibid*, para 58 O'Regan J (Glazebrook and William Young J concurring).

not found in the statute, but have rather been developed by Courts from principles such as general inconvenience.⁴¹ He noted that this has not necessarily made the law easy to understand.⁴² Therefore, he concluded:⁴³

It is precisely because of the unhappily technical character of patent law that in my view it is best to proceed – and it is certainly in the public interest to do so – wherever possible on the basis of clearly understood and articulated, basic principles. Patents after all are granted in the public interest – there is no other public policy justification for the monopoly – and it is only right that the public should understand as best it can be conveyed why it is that certain things are allowed and others are not.

The role of the public in consideration of economic and social policy issues is discussed in Part VI below. Before discussing that, however, it is important to discuss the international treaty obligation relevant to the definition of invention, particularly as an interpretation of those obligations is in part behind the opposing views on the role of the proviso and thus the role of economic and policy concerns in the patent law framework. Although New Zealand patent law has been modelled on British law and the interpretation of invention has been the subject of "judicial ingenuity"⁴⁴ patent law is also subject to international obligations.⁴⁵

III INVENTIONS AND INTERNATIONAL OBLIGATIONS

A Patents Must be Provided for "inventions in all fields of technology"⁴⁶

Lord Cooke has left patent law with a framework for interpreting "invention" and taking account of matters of economic and social policy concern, and in particular, that major steps are to be left to Parliament. Since *Wellcome* New Zealand has become a party to the TRIPS Agreement. Any interpretation of the definition of invention should be in accordance with this international obligation. It is therefore important to understand the extent of that obligation.

Fundamentally the TRIPS Agreement requires that patents must be provided for inventions.⁴⁷ The requirement that inventions be "in all fields of technology" does not mean that "invention" has no meaning and that everything is an invention.⁴⁸ The "all fields of technology" requirement is a

41 Ibid, para 106 Hammond J.

42 Ibid, para 110 Hammond J.

43 Ibid.

44 *Pharmac*, above n 8, para 21 Gault J for the Court.

45 The focus here is on substantive law obligations, which are primarily contained in the TRIPS Agreement, above n 9, rather than registration treaties such as the Patent Co-operation Treaty.

46 Ibid, art 27:1.

47 Ibid, art 27.

48 Ibid, art 27:1. The logical extension of Counsel's argument that the TRIPS Agreement means the proviso no longer applies is that invention has no meaning. That cannot be correct.

device to avoid discrimination against a particular field. If such discrimination were permitted it could unfairly alter a country's comparative advantage. So that if a country did not have its own manufacturing industry in a particular field of technology, the TRIPS Agreement does not permit it to discriminate against such industries by refusing patents for products or processes relating to that industry, in order to adjust its comparative advantage.⁴⁹ This non-discrimination is a core concept to the WTO Agreements of which the TRIPS Agreement is one. Interpreting the TRIPS Agreement as requiring that invention has no boundaries, because of the first part of article 27, is manifestly absurd as it ignores the other parts of that article and the well established principles of treaty interpretation that requires consideration of articles in their context.⁵⁰

The *Pfizer* Court asked whether the TRIPS Agreement meant that the concepts of "raising prices at home" and "generally inconvenient" were not part of the definition of "invention". Counsel for *Pfizer* submitted that the proviso could not survive New Zealand's joining of the TRIPS Agreement. O'Regan J rejected this. He held that "notwithstanding New Zealand's obligations under the TRIPS Agreement, the definition of 'invention' continues to incorporate the full text of section 6 of the Statute of Monopolies".⁵¹ Specifically, with regard to methods of medical treatment, counsel argued that the court could not ignore the obligation, under the TRIPS Agreement, to provide patents in all fields of technology on the basis of "circumstances of convenience such as the comparatively low level of medical research undertaken in this country or the particular method by which medicines are funded."⁵² This submission must be correct as such an interpretation would not be consistent with the non-discrimination principles set out in the latter part of that sub-article that "patent rights shall be available and ... enjoyable without discrimination as to the field of technology ... and whether products are imported or locally produced".⁵³ However, the general proposition that the proviso is not part of the definition of invention is not a logical interpretation of the meaning of the TRIPS Agreement. Courts cannot interpret the proviso in a trade discriminatory way but that is not the same thing as concluding the proviso is not part of the definition of invention. The proviso is a legitimate method of domestic law enacting a permitted exclusion under the TRIPS Agreement.⁵⁴

O'Regan J also pointed out that when Parliament amended the Patents Act 1953 in 1994, for the purpose of bringing the law into line with the TRIPS Agreement, Parliament did not think it necessary to amend the definition of invention. Notably, that was when it was well-known that

49 See *Canada – Patent Protection of Pharmaceutical Products* (17 March 2000) WT/DS114/R (Panel, WTO).

50 Vienna Convention of the Law of Treaties (23 May 1969) 115 UNTS 331.

51 *Pfizer*, above n 24, para 58 O'Regan J (Glazebrook and William Young J concurring).

52 *Ibid*, para 55 O'Regan J (Glazebrook and William Young J concurring).

53 TRIPS Agreement, above n 9, art 27:1, and see *Canada Pharmaceuticals*, above n 49.

54 Relevant exclusions can be found in the TRIPS Agreement, above n 9, arts 27:2, 27:3, and 30.

methods of medical treatment were not patentable and that *Wellcome's* ruling was partly based on the concept of general inconvenience. O'Regan J summarised the position:⁵⁵

It is notable that art 27:3(a) [of the TRIPS Agreement] specifically provides for exceptions for methods of medical treatment and it is possible that Parliament was content to leave the statute unamended in those regards, so that the exception which had applied as a result of the *Wellcome* decision continued to apply as art 27:3(a) permitted.

Anderson P in *Pfizer* stated after finding that methods of medical treatment are not patentable on the basis of "general inconvenience":⁵⁶

We add this caveat, however: we envisage little if any scope for exclusion, on such a basis, of inventions other than methods of medical treatment.

Anderson P did not explain this caveat. The reason for limiting the statute in that way is not clear. O'Regan J perhaps gave a partial explanation. He noted that a generalised exception to patentability based on inconvenience "could if broadly interpreted"⁵⁷ be wider than the TRIPS Agreement permitted. However, he gave no examples. What would be "too broad" would undoubtedly be subject to considerable debate. Problematically, however, IPONZ Hearings Officers have adopted Anderson P's statement, without consideration of other parts of the *Pfizer* judgments. The relevant IPONZ decisions are discussed in Part VII below.

One important point is that an exclusion from patentability might arise under the definition of invention in New Zealand law. The TRIPS Agreement does not define "invention". Therefore a domestic law definition of invention is a matter of national autonomy.⁵⁸ The only limitation is compliance with other parts of the TRIPS Agreement. Therefore, if the definition of intervention can result in an exclusion from patentability that exclusion must be compliant with the TRIPS Agreement exclusion provisions.⁵⁹

55 *Pfizer*, above n 24, para 56 O'Regan J (Glazebrook and William Young J concurring).

56 *Pfizer*, above n 24, para 7 Anderson P.

57 *Ibid*, para 57 O'Regan J (Glazebrook and William Young J concurring).

58 The TRIPS Agreement is an agreement of minimum standards. Countries are free to reflect the agreement in their law in anyway suitable to their national conditions, provided that the domestic law complies with the minimum standards. For a discussion of national "self-determination" see Graeme W Austin "Valuing 'Domestic Self-Determination' in International Intellectual Property Jurisprudence" (2002) 77 (3) Chicago-Kent Law Review 1155.

59 Under the TRIPS Agreement, the criteria of patentability are that inventions must be new, involve an inventive step and be capable of industrial application. These are also set out in article 27:1 of the TRIPS Agreement, above n 9. The practical effect of the TRIPS Agreement distinction between invention and these criteria can be important because it underscores the need to define the invention in order to assess patentability properly. See *Kirin Amgen Inc v Transkaryotic Therapies Inc* [2004] UKHL 46; Susy Frankel "A Patentable Invention: Will Current Proposed Law Reform Clarify Patentable Subject Matter?" (2005) 11

B Express Exclusions under the TRIPS Agreement

In addition to exceptions for methods of medical treatment, the TRIPS Agreement provides for other exceptions:⁶⁰

Members may exclude from patentability inventions, the prevention within their territory 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 not prohibited by their law.

It is beyond the scope of this article to traverse fully the scope of this provision's meaning.⁶¹ The WTO has, in the context of the services agreement, interpreted *ordre public* as any matter of important social policy.⁶² Exclusions from patentability based on the proviso concept of general inconvenience may be TRIPS Agreement compliant because of allowance for exclusions based on *ordre public* or morality.⁶³ The draft Patents Bill utilises both *ordre public* and morality.⁶⁴

IV A WELL DEFINED PATENT SYSTEM

For those inventors and investors who use the patent system to their advantage the concept of limiting patentability in any way usually causes concern. In seeking to ensure that courts and tribunals fully consider the meaning of "invention" my aim is not to limit patent law for the sake of it. My view is not "generally against patenting".⁶⁵ It is important that courts define the subject-matter of patent law to allow flexibility to cover new technology. However, such flexibility should not be at the expense of economic and social policy. Assessments of this kind require that the subject matter of patent law be defined. Those in the business of scientific research benefit from

NZBLQ 350; and Luigi Palombi "The Impact of TRIPS on the Validity of the European Biotechnology Directive" [2005] 1 JIBL 62.

60 TRIPS Agreement, above n 9, art 27:2 (emphasis added).

61 See Daniel Gervais *The TRIPS Agreement Drafting History and Analysis* (2 ed, Sweet & Maxwell, London, 2003).

62 *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (7 April 2005) WT/DS285/AB/R (Appellate Body, WTO).

63 For a discussion of how under the Patents Act 1953, s 17 the Commissioner can refuse a patent if it appears that the invention in respect of which the patent is made is contrary to morality, see *Pfizer*, above n 24, paras 65-66 O'Regan J (Glazebrook and William Young J concurring).

64 The Ministry of Economic Development released a draft Patent Bill for consultation. At the time of writing the draft has not been introduced as a Bill to the House of Parliament. The draft Bill can be found at www.med.govt.nz (accessed April 2008) [draft Patent Bill].

65 In referring to people who made submission to the Genetic Modification Inquiry regarding patents the report refers to some of these people as being "generally against patenting", *Report of the Royal Commission on Genetic Modification 2002*, available at <http://www.mfe.govt.nz> (accessed 1 March 2008) [*Genetic Modification Report*].

clear and practicable parameters of patent law. A careful consideration of what amounts to an invention and the standards of patentability ensures a rigorous patent system that is consistent with the goals of encouraging scientific endeavour and investment in research.⁶⁶ Patentees also benefit from greater certainty as to whether their patents are valid. Any less rigorous system is not only open to criticism, but is potentially contrary to the goal of encouraging innovation. If patentees and researchers cannot rely on patents because of uncertainty it is hard to see how patent law can achieve its goals.

The interpretation of the definition of invention in both *Pfizer* and *Wellcome* represent the view that the subject-matter of patent law has appropriate boundaries, and in particular, that the definition of invention is not open-ended in a manner that means that all technology *prima facie* meets the threshold of invention, regardless of economic or social policy concerns. The reasons primarily advanced for the open-ended approach, in *Pharmac*, are the absence of express statutory recognition of economic and social policy concerns in the form of limitations or exclusions from patentability.

A Express Exclusions from Patentability

The 1953 Act has no express exclusions to patentability, other than those in the section 6 proviso. The draft Patent Bill proposes a number of exclusions.⁶⁷ These include methods of medical treatment. The *Pfizer* Court observed that the inclusion in the Bill of an express exclusion would "in general terms, be to the same effect of the decision of this Court in *Wellcome*".⁶⁸ The *Pfizer* court also noted that such an exclusion was permissible under the TRIPS Agreement.⁶⁹ Counsel for Pfizer Inc submitted that because of the Parliamentary decision to impose an exception the *Pfizer* Court should overrule *Wellcome*. The Court rejected this submission noting that the proposal to make what was an unspecific exclusion into a specific exclusion was to confirm Parliament's intention that methods of medical treatment should not be patentable.⁷⁰

During amendments to the Patents Act 1953 in 1994 a back-bench Member of Parliament proposed introduction of a number of exclusions, including methods of medical treatment.⁷¹ This was rejected. Accordingly, counsel for Pfizer Inc argued that the opposite intention must have been

66 For a discussion of the justifications and goals of patent law see generally WR Cornish *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (4 ed, Sweet & Maxwell, London, 1999) 3-01-3-55.

67 Draft Patent Bill, above n 64, cl 14-15.

68 *Pfizer*, above n 24, para 69 O'Regan J (Glazebrook and William Young J concurring).

69 *Ibid.* See also TRIPS Agreement, above n 9, art 27:3.

70 *Ibid.*, para 70 O'Regan J (Glazebrook and William Young J concurring).

71 *Ibid.*, para 79 O'Regan J (Glazebrook and William Young J concurring).

present. The Court of Appeal also did not accept this submission.⁷² The judgment of Anderson P in *Pfizer* concluded:⁷³

Our overall view ... is that reform of this area of law is better undertaken through the parliamentary process. This would allow proper consultation with medical professionals and other organisations as well as the commercial interests which favour patentability and the formulation of considered reform proposals after that consultation process has taken place.

Should Parliament enact express exclusions, as proposed in the draft Patents Bill, that may give rise to a statutory interpretation issue of whether the presence of statutory exclusions means that Parliament intended that there be no other exclusions from patentability. It is questionable whether codifying some exclusions should mean that other exclusions cannot evolve as part of the courts' interpretation of the Act. Given the way in which the exclusion of methods of medical treatment has evolved it seems important that other exclusions are allowed to evolve in appropriate circumstances. Of course such evolution is only possible if there is a statutory basis for doing so, such as exists under the definition of invention incorporating the proviso, under the 1953 Act, or possibly under the provision in the draft Bill.

B Definition of Invention

It is important to update the definition of invention from, as Cooke J described it, "the archaic" language of the Statute of Monopolies.⁷⁴ Parliament should, however, be very careful not to enact new patent law without any definition of invention. The draft Bill retains the reference to the Statute of Monopolies, but only expressly to the aspect of "manner of manufacture". It states:⁷⁵

An invention is a patentable invention if the invention, so far as claimed in a claim, (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies...

This does not appear to refer expressly to the other parts of section 6, namely raising prices at home and generally inconvenient. Arguably the definition also refers to those aspects of the proviso because they are part of the concept of "manner of manufacture", although some case law separates the separation of the two concepts.⁷⁶ Parliament should, when the Bill is before the House, make its intention clear.

In any event, it remains possible that even without an express definition of invention the Courts will require an interpretation of the scope of any invention separately from other issues of

⁷² Ibid, para 79 O'Regan J (Glazebrook and William Young J concurring).

⁷³ Ibid, para 83 O'Regan J (Glazebrook and William Young J concurring).

⁷⁴ *Wellcome*, above n 4, 392 Cooke J.

⁷⁵ Draft Patent Bill, above n 64, cl 13.

⁷⁶ *NRDC*, above n 14, which was persuasive authority in *Pharmac*, above n 8.

patentability. The draft Bill does say "an invention is a patentable invention", retaining to a degree the two concepts.⁷⁷ Also there is precedent from the House of Lords emphasising the importance of the distinction that one should not attempt to assess patentability until one knows exactly what the invention for such an assessment is.⁷⁸ Furthermore, the exclusion on the basis public policy or morality has flexibility to allow the Courts room to follow the path commenced by Cooke J and developed by the *Pfizer* Court. That path is that where there is a division of views internationally it must be for Parliament to decide if new subject matters are an invention.

As discussed above, the *Pfizer* court agreed with Cooke J that the Statute of Monopolies proviso was part of the definition of invention. The proviso is a general exclusion to patentability because potentially a number of different exclusions may evolve from its parameters. *Wellcome* has provided an interpretation from which appropriate exclusions can evolve. *Wellcome* also asked the question who should make decisions about the scope of invention under patent law: the Courts or Parliament? The *Wellcome* answer was Parliament. The *Pharmac* approach, described above as being open-ended, also acknowledges the role of Parliament. However, this open-ended approach concluded that Parliament had allowed the courts to decide what an invention is, even when technologies raise issues of "general inconvenience".⁷⁹ In contrast, Cooke J's approach was that where there is a situation involving divergent approaches internationally, and it is difficult to say if any resolution is particularly right the Courts should resist the temptation "to break new ground ... it is best left to Parliament".⁸⁰ The combination of the two approaches raises questions as to who should decide what subject matter falls within the scope of invention and how they should decide it. A related question is what is the role of the public and the public opinion in such matters?

V THE ROLE OF THE PUBLIC AND PUBLIC POLICY IN PATENT LAW

A The Legislative Process

The legislative process has stages in which it calls for public submissions. These include policy making and consultation through the executive⁸¹ and the Parliamentary select committee process. Cooke J preferred that Parliament make decisions as to the scope of invention and certain technologies that raise economic or social policy issues. He did not suggest what Parliament should do and he did not take a specific view of the role of the public in such a process beyond the obvious,

77 Although there are some difficulties in that invention remains undefined. This provision is based on the equivalent Australian legislation, where invention also has a separate definition, see discussion in Frankel, above n 59.

78 *Kirin Amgen*, above n 59.

79 *Pharmac*, above n 8, para 14 Gault J for the Court.

80 *Wellcome*, above n 4, 391 Cooke J.

81 In relation to intellectual property policy the relevant part of the executive is the Ministry of Economic Development.

and therefore unstated, concept of Parliament being the elected representatives. As to whether methods of medical treatment were inventions under the 1953 Act he observed:⁸²

This is a plain example of a type of case that has been referred to more than once latterly by the House of Lords ... where any proposal for alteration ... "demands a far wider range of review than is available to the courts following our traditional and valuable adversary system".⁸³

For instance, not only is there the question of whether medical and surgical methods should be treated as a special subject in patent law – a question upon which the views of medical professional bodies would seem to be among those deserving consultation...

It is interesting that Cooke J took the view that it was proper for Parliament to decide, when he was not renowned for discouraging Courts from going places previously untrodden. In part this is a reflection of the nature of patent law, which he and McMullin J indicated was technically complex and driven by economic concerns rather than a satisfying juridical analysis.⁸⁴

As discussed above, it is incorrect to suggest that the scope of patentable subject matter is without boundaries because of international obligations. Patent law needs to appropriately reflect economic and social policy concerns. There will be debate over the extent of the statutory provisions in any particular circumstance, but the scope needs to be more clearly delineated by economic and social policy concerns. If Parliament does not do this and the Courts are not properly equipped to weigh the economic and social policy arguments beyond what is submitted in the adversarial process, then there is the danger that the economic and social policy needs of New Zealand will never be analysed in the patent law context.⁸⁵ A robust patent law with a defined scope that is appropriate for New Zealand will not be achieved if economic and social policy concerns fall between the cracks.

B The Process of Weighing Economic and Social Policy Concerns

1 The ethics of research and the patent social contract

Patent law faces certain difficulties because some of these concerns are about the nature of the scientific process and ethics of research. Such concerns do not belong exclusively to the patent system. Patent law is not the correct device to determine what is ethical research. The New Zealand Institute of Patent Attorneys ("NZIPA") submitted to the Genetic Modification Commission of

82 *Wellcome*, above n 4, 391 Cooke J.

83 Cooke J is quoting *Pirelli General Cable Works Ltd v Oscar Faber & Partners* [1983] 1 All ER 65, 72 Lord Fraser, who is quoting *Miliangos v George Frank (Textiles) Ltd* [1976] AC 443, 480 Lord Simon.

84 *Wellcome*, above n 4, 389 Cooke J.

85 I have argued elsewhere that this is what occurred in relation to the patentability of Swiss claims, see Frankel, above n 59.

Inquiry that patent law should not concern itself at all with such issues.⁸⁶ Patent law is not the only relevant institution to guide the ethics of scientific research, but the view that such matters are irrelevant to patent law is not correct. Patent law is a social contract under which, in exchange for the disclosure of information through the patent system, the patent is a reward. Patent law should not reward the economically disadvantageous or something that is contrary to social policy. If it does so it calls into question the legitimacy of its foundation. The patent system cannot control what people choose to research and, in addition, the grant of a patent is not the equivalent of a right to use an invention that may be subject to other regulatory controls, such as the Medicines Act 1981 or the Hazardous Substances and New Organisms Act 1996. However, the patent system with its foundation in the concept of reward and its justification on the basis of a social contract should not be blind to what it rewards.

While it is true that patent law cannot determine the ethical boundaries of research the role of patent law in research decisions should not be underplayed. Advocates in support of increasing the scope of patent law may cite, in favour of their argument, the necessity of its protection in order to carry out research. The protection it is said is needed as an appropriate reward to encourage research and investment. Financial investors in research will often only fund such research if there is the apparent security of patents in their investment. Patent law does not, however, define the ethics and parameters of scientific research. As discussed above there are exclusions from patentability and the scope of invention that may involve considerations of issues of social policy. Such exclusions are permitted internationally precisely because of the recognition of the limitations of patents and their social contract function.

2 *The genetic modification inquiry and public consultation*

New Zealand has also seen patent law discussed in the context of the Royal Commission on Genetic Modification.⁸⁷ The Royal Commission held extensive public consultation in the form of meetings, submissions and hearings. The Commission heard from a number of different witnesses on aspects of morality and ethics of patenting in fields involving genetic modification. The Commission purported to weigh those competing values and made some recommendations, including that the law provide for a specific exclusion of human beings from the scope of patentability. The report acknowledged that the combination of IPONZ policy to refuse patents for humans and the prevention of substances found in nature being patentable should mean that "humans, parts of humans, or a human gene found in its natural host" are not patentable.⁸⁸ Some of the apparent public misunderstanding about whether human beings are patentable arises from the fine interpretation of concepts like "a human gene found in its natural host". Although such a gene is

⁸⁶ *Genetic Modification Report*, above n 65, chapter 10, 281.

⁸⁷ *Ibid*, chapter 10.

⁸⁸ *Ibid*, 284.

not patentable, and humans cannot be patented, patents do exist in relation to certain aspects of humans, in particular, patents that relate to gene sequences.⁸⁹ There remains international division, particularly between the United States and the EU, over the scope of patents in relation to genetic sequences.⁹⁰ The debate over patentability of such matters initially centred on the issue of novelty. The path of discovery of a genetic sequence is a difficult path involving a vast amount of skill. However, the results of such research remain primarily a discovery rather than something which is novel. In the United States this debate has been resolved by allowing the patent for a gene sequence in relation to a particular use. The "breast cancer gene" is an oft-cited example.⁹¹ Cooke J cited international division over what might or might not be the correct approach as his evidence of why Parliament, rather than the courts, should decide what is patentable. Such internationally diverse views over genetic modification may have underlain the reasons for that inquiry, but the inquiry did not assess the international division over the scope of patent law and so Parliament needs to do so.

The NZIPA submitted to the Commission that:⁹²

...if biotechnology is to be part of New Zealand's economic future, maintenance and improvement of intellectual property protection for genetic modification and genetically modified organisms is essential. If patents for the products of research on genetic modification and genetically modified organisms could not be obtained in New Zealand, a number of negative economic outcomes would follow, including:

- increased cost for New Zealand to access international intellectual property, with less bargaining power from reciprocal information exchange
- the cost of difficulty in maintaining information as a trade secret
- exploitation of unprotected New Zealand information and products by others
- loss of revenue from licensing and royalties
- loss of revenue consequent on loss of competitive advantage.

Opposing submissions were also made to the Commission of Inquiry, including the impact on science and technology.⁹³ The purpose here is not to assess the issues relating to genetic modification, but to examine the context of the submissions as public consultation in relation to the

89 Ibid.

90 See generally Philip W Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (4 ed, Oxford University Press, Oxford, 2004).

91 See US Patent Nos 5,747,282 and 5,709,999. See also discussion in Timothy J Ohara "Patenting the Diagnosis of a Disease: The Scope of Patentable Subject Matter Based on *Labcorp v Metabolite Labs*" (2007) 38 Golden Gate UL Rev 139.

92 *Genetic Modification Report*, above n 65, Chapter 10, 280.

93 Ibid, Chapter 10, 278.

scope of the patent system. The above NZIPA submissions reveal some potentially valid economic arguments; however, there is some missing data and analysis, such as why costs might increase. It is not clear why patent owners would refuse to license other areas of intellectual property protection because they cannot obtain protection for patents that involve an aspect of genetic modification. And even if that refusal would occur what impact would that have on the New Zealand's economy? While such matters cannot be predicted with certainty they can be assessed in more detail.

Similarly, the Dairy Board submitted that New Zealand ought to provide patents for inventions in the field of genetic modification because, for example, the Roslin Institute in Edinburgh owns many aspects of intellectual property for cloned or transgenic animals and the tools used for this research.⁹⁴ Therefore the New Zealand dairy industry needs patent protection in order to bargain when seeking to use intellectual property owned by others.⁹⁵ This is a compelling economic argument, but again requires closer examination and a weighing of costs and benefits. The Commission, in recognition of the moral and ethical arguments that arise in the field, did not weigh those concerns itself; rather it recommended the establishment of Toi te Taiao: the Bioethics Council, which it suggested that IPONZ could consult when faced with ethical questions in applications for patents.⁹⁶

Ultimately the viewpoints concerning patentability of genetically modified products and processes may be incompatible, but whatever viewpoint prevails, it should be based on a full economic and social policy analysis rather than statement of negative outcomes apparently without in-depth supporting data. If the Royal Commission on Genetic Modification is not going to undertake such an inquiry and recommends that IPONZ do so, then either IPONZ or the Parliamentary system ought to actually do so.

VI ISSUES OF EXCLUSION FROM PATENTABILITY ON NEW ZEALAND'S HORIZON

Cooke J, in finding that the courts should leave the scope of invention to Parliament, had great foresight beyond the case in front of him. During his career he delivered several judgments regarding the Treaty of Waitangi.⁹⁷ He did not obviously consider the relationship between the Treaty and patent law, as other issues were before him. The connection has been articulated as a result of proceedings before the Waitangi Tribunal, in what is known as the Wai 262 claim. An aspect of that claim is that patents should not be granted in respect of certain taonga protected under article II of the Treaty.⁹⁸ Some patents, or plant variety rights, may already exist in relation to

94 Ibid, 279.

95 Ibid.

96 Ibid, 281.

97 See Paul McHugh in this volume.

98 Statement of Issues in Wai 262, available at www.waitangitribunal.govt.nz (accessed 22 April 2008).

taonga. Whether the Crown has a Treaty obligation to protect any taonga, such as Maori traditional knowledge or indigenous flora and fauna, remains to be determined and its effect on patent law remains to be seen.⁹⁹ The Wai 262 claim exemplifies how the policy-weighting process of what is patentable lies outside the scope of interpretation of the definition of invention. The statutory framework for exclusions from patentability and the role of "invention" in the Treaty partnership are yet to be articulated. One question left hanging is how the Statute of Monopolies proviso, or any equivalent successor, applies to exclusions other than methods of medical treatment.

A Is There any Ongoing Role for the Proviso?

The open-ended approach to the definition of invention was not advocated by Cooke J in *Wellcome* or by the *Pfizer* Court of Appeal. Those cases concerned the patentability of methods of medical treatment. With the exception of Anderson P's obiter dictum caveat in *Pfizer*, none of the judges confined the conclusion, that the Statute of Monopolies proviso was part of the definition of invention, to methods of medical treatments. The proviso is potentially wide¹⁰⁰ and may not be confined to methods of medical treatment. Anderson P's words should be interpreted as is a cautionary note about its application.

The Court of Appeal's finding that the proviso is part of the definition of invention binds the High Court and IPONZ to consider the full ambit of section 6 of the Statute of Monopolies when assessing whether something, particularly new subject matters, are inventions within section 2 of the 1953 Act. Yet such an analysis is conspicuously absent from IPONZ decisions that "break new ground". Two examples are the patenting of Swiss claims relating to dosage regimes¹⁰¹ and the patentability of data structures.¹⁰² The robustness the patent system ought to ensure that the full scope of the definition of invention, as interpreted by successive Courts of Appeal, is applied to the examination of patent applications.

B The Limits of IPONZ's Jurisdiction

When a party applies for a patent in New Zealand the benefit of the doubt goes to the patentee, meaning that something should be patented unless it clearly is not permitted under the legislation.¹⁰³ *Pharmac* sets out the process of examination of a patent application.¹⁰⁴ The

99 The hearings for the Wai 262 claim were completed in June 2007. At the time of writing the Waitangi Tribunal has yet to complete its report.

100 *Pfizer*, above n 24, para 57 O'Regan J (Glazebrook and William Young J concurring).

101 *Patent Application No 501807, Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd* (31 January 2006) Assistant Commissioner Hazlewood [*Merck v Arrow*] and *Patent Application No 539505, Genetech Inc* (15 December 2006) Assistant Commissioner Popplewell [*Genetech*].

102 *Patent Application No 535069, Microsoft Corporation* (23 October 2006) Assistant Commissioner Popplewell [*Microsoft*].

103 *R v Patents Appeal Tribunal, ex parte Swift and Co* [1962] RPC 37 cited in *Pharmac* above n 8, para 15 Gault J for the Court.

examination includes the issue of whether or not something is an invention. The examiner asks whether an invention is novel but not whether it is obvious. Lack of inventive step is a ground for third party opposition.¹⁰⁵ Other grounds, such as lack of utility, are grounds for revocation of a patent.¹⁰⁶ The limit on examination is part of the rationale for giving the benefit of the doubt to the patentee. Lord Parker stated about the then equivalent United Kingdom law:¹⁰⁷

...the function of the [Commissioner] ... under ... of the Act is not to decide finally whether an alleged manner of new manufacture is actually patentable. Rather their function is to refuse to allow applications to proceed which on no reasonable view could be said to be within the ambit of the Act. It is true that on the face of [the] section ... there are no express words to this effect, but it seems to me that looking at the scheme of the legislation as a whole that must be the position. Thus if one goes back to section 2 of the Statute of 1623 it will be seen that from the very beginning it is for the High Court to determine actual patentability

It is important to appreciate that Lord Parker was distinguishing between patentability and invention. Lord Parker did not suggest that the Commissioner could not decide if something was an invention or not. Additionally, it is not strictly correct that issues of patentability are not dealt with during examination in New Zealand. Most importantly, however, Lord Parker is emphasizing that where a known type of patent application is made, any doubt about its novelty must be resolved in favour of the applicant. It is not a sensible interpretation of Lord Parker's words to suggest that any doubt about whether the subject matter of an application triggers concerns relating to the section 6 proviso means that the benefit of the doubt goes to the applicant not to consider the proviso. The section 6 proviso of generally inconvenient or raising prices at home is simply a trigger that something may not be an invention under the Act. Doubt over whether a something should be regarded as an invention because of economic or social policy concerns does not raise a benefit of the doubt for the patentee of that kind Lord Parker referred to. Such concerns have the function of removing the application from the clear scope of invention and therefore until Parliament or the Courts resolve otherwise the Commissioner should not patent it. The function of the presumption of the benefit of the doubt to the patentee does not extend to "updating" the law in New Zealand, either because Parliament had not legislated or because a higher court has not yet departed from its earlier decisions. Lord Parker anticipated that applications not stop at the Commissioner level, but that there be another level of review in the High Court. In the absence of the likelihood of another level of review, a point expanded on below, it is incumbent upon IPONZ to weigh the points of "general inconvenience". In doing so it should either decline to patent a new subject matter that raises

104 *Pharmac*, above n 8, paras 11-15 Gault J for the Court.

105 Patents Act 1953, s 21(e).

106 *Ibid*, s 21.

107 *Swift & Co*, above n 103, 46 Lord Parker.

significant economic or social policy issues until Parliament has indicated its view, or at the very least seek advice from appropriate bodies, such as the Genetic Modification inquiry recommended. Most patent applications will not raise any proviso issues. IPONZ need only seek advice where such concerns arise because the patentable subject matter raises unforeseen economic and social consequences. The applicant of a patent for allowing a dosage regime to be patentable in Swiss claim form cited Lord Parker.¹⁰⁸

1 Swiss claims for a dosage regime

The application in *Merck v Arrow*, was for a known medicament formulated for a particular dosage in the Swiss claim form. The only novelty that could exist in such a claim is the new dosage. In this sense such an application differs from the Swiss claim allowed by *Pharmac* because the medical purpose of the active ingredient is known. The Assistant Commissioner held that as a general principle the type of application was patentable. On the facts the application failed because the invention was obvious and did not involve an inventive step. The High Court reversed this finding.¹⁰⁹ The Assistant Commissioner stated:¹¹⁰

I believe there can be inventiveness in improving existing therapies and this is patentable by way of Swiss claims.

IPONZ subsequently issued guidelines indicating that a dosage regime was a method of medical treatment and consequently not patentable.¹¹¹ The rationale for these guidelines was first that the decision in *Merck v Arrow* was at odds with an earlier decision, *Abbott Laboratories*, of a different Assistant Commissioner, who had held a dosage regime to not be patentable.¹¹² The guidelines state:¹¹³

In light of the Court of Appeal's reluctance to broaden the scope of medical treatment in *Pfizer* ... the present position of the Office concerning Swiss-type claims is to follow the more conservative approach in *Abbott Laboratories* wherein was stated: "It seems to me that claims ... by claiming the use of a known compound in the manufacture of a medicament with a known pharmaceutical activity ... do not comply with the definition of 'Swiss claims' [upheld] in *Pharmac*."

¹⁰⁸ *Genetech* above n 101, 8 Assistant Commissioner Popplewell.

¹⁰⁹ *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd* (29 September 2006) HC WN CIV-2006-4585-817 Harrison J.

¹¹⁰ *Merck v Arrow*, above n 101, 44 Assistant Commissioner Hazelwood.

¹¹¹ IPONZ "Guidelines for the Examination of Swiss-type Claims" (15 September 2006), cited in *Genetech*, above n 100, 5 Assistant Commissioner Popplewell ["IPONZ Guidelines"].

¹¹² *Patent Application No 510328, Abbott Laboratories* (9 June 2003) Assistant Commissioner Popplewell.

¹¹³ "IPONZ Guidelines", above n 111.

Next Genentech applied to patent another dosage claim in Swiss claim form. There Assistant Commissioner Popplewell held that the application was patentable, effectively changing his mind from his decision in *Abbott Laboratories* because of so-called international developments.¹¹⁴

In both *Merck v Arrow* and *Genetech* the divergence of international approaches on the patentability of dosage regimes is discussed. In *Genetech* the Hearing Officer noted that the only contrary view to dosage regimes being patentable is an English Court of Appeal decision, *Bristol Myers Squibb v Barker Norton Pharmaceuticals*.¹¹⁵ But in neither decision does this result in the Assistant Commissioner connecting that divergence, as Cooke J did in *Wellcome*, to the definition of invention. In *Merck* the Statute of Monopolies proviso is mentioned in relation to methods of medical treatment, but the application was treated as not being a method of medical treatment that is excluded from patentability, but a type of Swiss claim. Similarly in *Genetech* the Assistant Commissioner describes the application for a dosage regime as a Swiss claim and then in support of patentability is "conscious" because Anderson P suggested that the Statute of Monopolies proviso was unlikely to apply beyond methods of medical treatment.¹¹⁶ An application being in Swiss claim form does not make it the equivalent of the Swiss claim permitted in *Pharmac*. In my view, the Assistant Commissioner did not give full consideration to the introductory parts of the paragraph that contains part of Anderson P's caveat: "for the reasons expressed in the judgements of Hammond and O'Regan JJ."¹¹⁷ Those reasons should have been discussed in *Genetech*, rather than Anderson P's few words being interpreted in isolation from its reasoning. What this sweeping reliance on Anderson P's opening ignores is the very point that the dosage regime is arguably a method of medical treatment which the Court of Appeal found to be excluded from patentability. *Pharmac* was limited to the type of Swiss claim before it, being a new use of a known pharmaceutical substance. And in light of the Court of Appeal's approach in *Pfizer* a tribunal of first instance at IPONZ cannot realistically take the view that the *Pfizer* decision does not bind it to treat a dosage application as a method of medical treatment that is not patentable. Even if one reads the subject matter of new dosage claims as falling between the rationales of *Pharmac* and *Pfizer* there is sufficient direction in the *Pfizer* judgments that such a claim might not be patentable; yet the details of that judgment were not discussed.¹¹⁸

At the very least IPONZ should not decide such a matter when there is international division of the very type Cooke J mentioned in *Wellcome*, because in the face of such international division,

114 *Merck v Arrow*, above n 101.

115 *Bristol Myers Squibb v Barker Norton Pharmaceuticals* [2001] RPOC 1 cited in *Genetech* above n 101, 15 Assistant Commissioner Popplewell. Assistant Commissioner Popplewell notes that the English Court of Appeal is highly persuasive but not binding on him.

116 *Genetech*, above n 101, 17 Assistant Commissioner Popplewell.

117 *Pfizer*, above n 24, para 7 Anderson P.

118 *Ibid*, paras 51-62 O'Regan J (Glazebrook and William Young J concurring); 122-123 Hammond J.

New Zealand is not obliged to adopt one position over another. Also, as patent law involves questions of economic importance to a country the size of New Zealand those economic questions should be considered. The statutory definition of invention incorporating the section 6 proviso as it does means that Parliament has intended that issues of general inconvenience are assessed. IPONZ is not the place to do that and it should not allow patents for new subject matters simply because it does not have the capacity to evaluate those concerns.

2 *Data structures*

In 2006 Microsoft applied to IPONZ for a patent for a data structure.¹¹⁹ The field of technology referred to in the patent specification was:¹²⁰

The invention relates generally to computer systems, and more particularly to data structures for the processing of graphical and other video information for display on computer systems.

The applicant submitted that the application is not for mere intellectual information, but that the "data structure was very complex and interacts with the operating system to produce a new and beneficial result".¹²¹ The Assistant Commissioner's decision discusses the definition of invention and the concept of "manner of manufacture" contained therein. It utilises the guidance of the High Court of Australia in *NRDC* to consider the meaning of manner of new manufacture, which is part of the definition of invention, and refers to the adoption of *NRDC* in *Pharmac*. Insofar as the concept of manner of manufacture is concerned such an approach is undoubtedly correct, but manner of manufacture is only part of the definition of invention. IPONZ ignores the other parts of the provision. The main reason for the decision appears to be the view that it is in keeping with United States developments to allow the application.¹²² The Assistant Commissioner acknowledges that the definition of invention, under section 2, is not the same in the United States, but he is nonetheless comfortable in following the United States approach because of certain similarities between the law in relation to old cases that are allegedly factually analogous.¹²³ There is no international agreement over the patentability of such data structures. This is exactly the kind of international divergence that according to Cooke J in *Wellcome* means that Parliament should decide. The decision contained no discussion of any economic or social policy concerns as to data structures. The applicant's case was that the utility of the data structure makes a useful contribution and is therefore patentable. But this does not address the concepts of "raising prices at home" or "generally inconvenient" which are the triggers for considering concepts such as economic and

¹¹⁹ *Microsoft*, above n 102.

¹²⁰ *Ibid*, 2 Assistant Commissioner Popplewell.

¹²¹ *Ibid*, 8 Assistant Commissioner Popplewell.

¹²² *Ibid*, 12-13 Assistant Commissioner Popplewell. Such patents are in fact disputed in the United States.

¹²³ *Ibid*, 13 Assistant Commissioner Popplewell.

policy concerns. IPONZ needs to at least address these aspects of the definition of invention. It may conclude that there are no significant concerns of such a nature. If IPONZ does, however, conclude that the new subject matter raises such concerns it should decide that such matters are not patentable until Parliament says so. Unless IPONZ takes this approach it is acting contrary to *Wellcome* and the *Pfizer* Court of Appeal. IPONZ cannot ignore parts of Court of Appeal binding judgments. Perhaps, however, the real difficulty in such situations is that only an applicant appears before IPONZ. This is discussed in the next part.

VIII THE IMPORTANCE OF A FLEXIBLE BUT NOT UNLIMITED DEFINITION OF INVENTION

I do not advocate that certain subject matters should not be inventions. Indeed the TRIPS Agreement itself prohibits discrimination purely based on subject matter.¹²⁴ That said, the TRIPS Agreement endorses national autonomy to consider the limitations of invention. The approach called for is not to say that patents should not be granted but that when new subject matters are introduced they ought to be qualitatively evaluated against the standard of invention, which includes assessment and weighing of relevant economic and social policy concerns.

It is important to appreciate that invention has a flexible definition and the real issue is how flexible it is. It is not so much that the Statute of Monopolies defines the meaning of invention, but that the scope of the invention is intended to develop in accordance with consideration of the policy of the Statute of Monopolies. I am not advocating against patent law encompassing new technology, simply, that if it is appropriate to expand the subject matter of patentability it must be done in a considered way. Such an approach ensures that the limits of invention are reasoned in a way that involves assessment of varying points of view in the national interest of New Zealand. To illustrate the necessity of weighing competing view points it might be helpful to compare the definition of invention, as the gate to a patent, to the equivalent gate to copyright.

The concept of invention for the purposes of this analysis is the equivalent of "copyright work" rather than the specific category of work. Before originality is assessed a copyright work needs to be categorised as literary, artistic, and dramatic and so on.¹²⁵ Each category of work has a definition, but over the years those definitions have been treated with remarkable elasticity. The category of artistic work, for example, has been expanded to incorporate industrial designs and the category of literary works now incorporates computer programs. There are, however, a number of important differences between the flexibilities of copyright work categories and the flexibility of invention in patent law. First, invention is not broken down into subject matter groupings precisely because it is more flexible if it is not. Any attempt to delimit invention through subject matter categories comparable to copyright might be contrary to the TRIPS Agreement if it resulted in subject-matter

124 See discussion in Part III above.

125 Copyright Act 1994, s 16.

discrimination.¹²⁶ Most importantly, however, the categories of subject matter in copyright and their expansion are frequently subject to judicial scrutiny. As copyright does not have a registration system the legislature have clearly given the courts the power to interpret the scope of categories of work within the framework of the statute. Whenever a copyright right is asserted against a person that person always has the possibility of challenging that assertion, including the category of work. The litigation process and the courts are the forum for that challenge. Even though litigation is not always a practical alternative the ability for the scope of copyright to be challenged in the adversary system is important. The absence of registration means that the parties are on a more even footing until the courts decide whether copyright subsists or not.

The scope for a third party challenge to the right does not exist to the same degree in the patent system. Under the Patents Act 1953 there is a limited opportunity for pre-grant opposition.¹²⁷ The draft Patents Bill proposes abolition of this.¹²⁸ If a patent infringement action is brought it is open to the alleged infringer to challenge the validity of the patent and to seek its revocation.¹²⁹ Revocation of a patent may be an available action outside of an infringement dispute, however, without a doubt the existence of the patent registration is a much greater deterrent to litigation. Copyright allows for similar works, which are different expressions of the same idea, to co-exist, whereas patents must be novel and cannot be so closely related. Unlike copyright, competing inventors can search for existing patents and be deterred from their line of research because of existing patents, or a researcher may pay royalties to use an invalid patent because it is cheaper than mounting a full scale validity challenge. Ideally, when new subject matters are introduced in a patent application that is exactly the moment for a challenge to patentability to be fully considered, rather than after the fact. There are practical considerations why this does not occur in the examination process in New Zealand.¹³⁰ Although those limitations to the examination system can be justified that is precisely why a rigorous approach to the definition of invention is important. As the Court of Appeal has held that the Statute of Monopolies proviso is part of the definition of invention then at the application stage those parts of the definition should be considered and should be seen to be considered.

Standing to challenge patentability is potentially problematic in patent law. If IPONZ decides a general category of invention is patentable, as occurred, for example, in relation to dosage claims, then there might not be an obvious party with standing to appeal such a decision. If patentability is

¹²⁶ See discussion in Part III above.

¹²⁷ Patents Act 1953, s 21.

¹²⁸ Draft Patent Bill, above n 64, which does not propose re-enacting the current opposition section in Patents Act 1953, s 21.

¹²⁹ Patents Act, 1953, ss 41-42.

¹³⁰ See discussion above.

denied then the applicant has a right of appeal.¹³¹ IPONZ, therefore, has the role in the examination and application process to represent any third party public interest insofar as those interests are incorporated into the Patents Act 1953. However, if the applicant is successful and a third party disagrees with IPONZ then the only way to review the decision, short of waiting for an infringement action, is through judicial review. Pharmac sought judicial review of the IPONZ decision to allow Swiss claim patents. In that case Pharmac had a particular interest in the price of pharmaceuticals. It is not always clear that in relation to new technologies there is anyone with a similar interest and therefore motive for judicial review of a class of patents.¹³²

In any event, where a new type of patent raises significant issues of economic and/or social policy concern then the full review of competing concerns should take place. The statute does not clearly provide for a robust mechanism by which that can take place at IPONZ. The courts are not the appropriate forum because there may be more relevant views than those that emerge in the adversarial process and therefore the weighing of issues should be a matter for the legislative process.

VII CONCLUSION

Cooke J in *Wellcome* opened the debate about the role of social policy concerns in the scope of patent law. Patent law is an important factor in research and innovation. Patents alone do not drive decisions as to what is researched. Nevertheless patents play a significant role in delineating what others are free to research and what others might be required to license in order to research related areas. The value of patents in obtaining finance for research is also important. Certainly it can be said that ethical decisions about research activities are not primarily driven by patent law. One approach, that *Pharmac* illustrated, is that the registration system should not ask questions about economic benefits and social policy issues relating to scientific research because such concerns belong outside of the patent system. Even if the patent system is not the central place for making ethical decisions about research the patent system should not reward what is disadvantageous to New Zealand's economic and social policies. The approach of Cooke J in *Wellcome* and the development of Cooke's interpretation in *Pfizer* concluded that at the legislative stage of patent policy significant questions of economic and social policy ought to be discussed, and that when significant economic questions arise in the registration system in relation to new types of invention then Parliament must decide whether such new subject matters are patentable.

The evolution of the Swiss claim debate highlights the problems with the current system. Gault J's approach was that the open-ended nature of the definition meant Swiss claim applications could be patentable. It was not, in his view, the role of the courts to discuss the economic and other policy

¹³¹ Patents Act 1953, s 97.

¹³² Although as Lord Cooke took a liberal approach to standing in judicial review, theoretically obtaining standing might be relatively straightforward: see Dean Knight in this volume.

issues surrounding such patents. The economic and social policy issues relating to Swiss claim patents were not weighed at the legislative stage, were not considered relevant in the Court of Appeal and were not fully discussed at the IPONZ registration stage. That example seems in some way to advocate that such policy discussion is not to take place at all, in spite of the intention of Parliament evidenced by including the proviso, as the basis for consideration of those issues, in the definition of invention and in spite of the obvious relationship between patents and economic benefit.

If economic and social policy concerns should only be addressed in the legislative process, one question is how that should occur. The executive might undertake a policy discussion and the legislature has the role of debating proposed laws before Parliament and at the select committee stage. Difficulties may arise at both stages because patent law can have the air of technical and scientific complexity.

An open-ended definition of invention is important for the functioning of patent law, but that open-ended definition should not be used to circumvent the policy debate. Cooke J has left us with a valuable lesson that the legislature has an important role in delineating the economic and social policy concerns of developing science and technology and the question of how the patent system responds to that.