
**THE CONTINUING SAGA OF SWISS-TYPE CLAIMS:
THEIR SCOPE AND POTENTIAL APPLICABILITY TO
PHARMACOGENOMICS**

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Physicians pour drugs of which they know little to cure diseases of which they know less, into humans of whom they know nothing.

Voltaire (1694-1778)

INTRODUCTION

The face of drug development as we know it is changing. As the research and development strategies of drug companies rapidly change direction, so too do the practices of patent offices globally. New medical entities are now rarely developed, rather the focus has shifted to establishing new uses for existing compounds. Patenting these new uses has become a problem for both the legal and pharmaceutical worlds.

There are many complexities at the interface between patent law and the pharmaceutical industry. Patent offices worldwide are currently forced to walk a thin line by balancing patent protection available to pharmaceuticals with ensuring these companies do not receive an undeserved windfall. While patents provide drug companies with incentives to continue research and development, consequent costs to society must also be considered.

In response to the challenges presented by the changing drug development field, the 'Swiss-type claim' has evolved. This is a specific form of patent claim employed by the pharmaceutical industry in order to extend the protection afforded to pharmaceuticals. It is described as an 'artificial'¹ form of claim, which has been devised to provide patent protection for inventions which otherwise would fail to acquire such protection. The part such claims will play in the next decade depends on the degree to which patent offices will allow patent laws to be manipulated.

This paper reviews existing patent laws and examines how they are interpreted and extended as they struggle to adequately keep abreast of the changes in the focus of drug development. It is divided into three parts, loosely exploring the development, present situation and future application of 'Swiss-type claims'.

¹ *Merck & Co Inc's Patent* [2003] FSR 498 (Pat. Ct.), para 80 (Jacob J).

Chapter I provides an overview of the patent system, specifically focusing on the ‘methods of medical treatment’ exclusion to patentability. This exception to patentability precludes the acquirement of patents for new uses of existing pharmaceuticals. The exclusion exists in a number of countries worldwide, with the rationale that medical practitioners’ activities ought not to be fettered by patents over methods of treatment. Determining the extent to which the *use* of pharmaceuticals constitutes a method of medical treatment has caused a number of difficulties over the years.

Chapter II analyses the evolution of Swiss-type claims and their international status and scope today. For drugs whose active chemicals are known and have a known use, a ‘direct’ patent claim cannot confer any protection to second or subsequent uses. Consequently, starting 25 years ago, clever wording of the patent claim has eroded the methods of medical treatment exclusion by indirectly permitting the patenting of drug regimes. Further erosion of this exclusion has occurred through the subsequent extension of the scope of Swiss-type claims. The legality of these claims and of possible alternatives is analysed.

Chapter III explores the emergent field of pharmacogenomics from an intellectual property viewpoint. The evolution of pharmacogenomics promises to revolutionise healthcare by personalising drug treatment. The current patent protection available in the field of pharmacogenomics will be examined, followed by analysis of whether Swiss-type claims in their extended form will provide comprehensive patent protection to pharmacogenomic inventions of the future.

I. THE PAST: PATENT PROTECTION FOR METHODS OF MEDICAL TREATMENT

1.1 The New Zealand patent system

A patent can be described as a ‘social contract’² between an inventor and society. In exchange for disclosure of the invention to the public, the inventor is granted a temporary monopoly in respect of that invention. The grant of a patent gives the registered proprietor the exclusive right to make, use or sell the invention in New Zealand for a term of 20 years and to authorise others to do the same.³ In exchange, the invention is disclosed to the public and once the patent expires it becomes freely available for others to use.

The patent law of New Zealand is set out in the Patents Act 1953. This Act has been amended several times, most notably in 1994 following New Zealand’s accession to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Extensive reform of the Patents Act 1953 has been proposed in the form of the Patents Bill 2008.⁴ At the time of writing, this Bill was before the Commerce Committee with their report due in November 2009.⁵

Obtaining a patent can be a prolonged and complicated process. A patent application accompanied by a complete specification is filed with the Intellectual Property Office of New Zealand (IPONZ). The Commissioner of Patents refers the application to an

² S Frankel, “Lord Cooke and Patents: The Scope of ‘Invention’” (2008) 39 VUWLR 73, 86.

³ I Finch, *James & Wells Intellectual Property Law in New Zealand* (Thomson Brookers, 2007) 30.

⁴ Patents Bill 2008, no 235-1.

⁵ New Zealand Parliament, Business before the Commerce Committee, available at <http://www.parliament.nz/en-NZ/PB/SC/Details/Commerce/1/d/3/00DBHOH_BBSC_SCCO_1-Business-before-the-Commerce-Committee.htm> last accessed 6/10/09.

examiner.⁶ If an application is accepted and published in the Patent Office Journal, there are three months in which opposition proceedings can be initiated.⁷ Once the patent has been granted, it may be revoked upon application to the High Court⁸ or to the Commissioner of Patents.⁹

The subject-matter of a valid patent in New Zealand must be a manner of manufacture, be novel, be useful and involve an inventive step. Currently, patent applications are examined to ensure the subject-matter of the claim is a manner of manufacture and is novel. Lack of inventive step (obviousness) is a ground for opposition and revocation proceedings, whereas utility is only a ground for revocation. The approach in New Zealand therefore is more lenient than in other jurisdictions where there is examination of each of the requirements of patentability before an application is accepted. Changes to this process are proposed in the Patents Bill 2008. Although the requirements of patentability remain the same,¹⁰ examination for all four requirements would be mandatory under the Bill.¹¹ Therefore following enactment of this Bill, examination will be considerably more rigorous in New Zealand.

The Patents Bill 2008 defines each of the criteria for patentability. An invention will be novel if it does not form part of the prior art base;¹² it will involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the prior art base;¹³ and it will be useful if it has a specific, credible and substantial

⁶ Patents Act 1953, s12.

⁷ *Ibid.*, s21.

⁸ *Ibid.*, s41.

⁹ *Ibid.*, s42.

¹⁰ Patents Bill, above n 4, cl 13.

¹¹ *Ibid.*, cl 60.

¹² *Ibid.*, cl 6.

¹³ *Ibid.*, cl 7.

utility.¹⁴ As in the Patents Act 1953, ‘manner of manufacture’ is construed within the meaning of section 6 of the Statute of Monopolies.¹⁵

The complete specification filed with IPONZ includes a claim, or claims, which define the scope of protection conferred by a patent. Two forms of claim are considered in this paper. ‘Product’ claims provide protection over physical entities or things. In contrast, ‘use’ claims protect activities or actions (such as methods, processes or uses). An important distinction is that product patents protect all commercial uses of the product within the 20 year term; method or use patents protect only that particular use. If a product is already known in the field, a claim for the use is all that is possible.¹⁶

1.2 The importance of patents in the field of pharmaceuticals

There is little doubt that patents are of particular significance in the pharmaceutical field.¹⁷ Indeed, the pharmaceutical industry is one of the few industrial sectors in which patents are an effective means to capture returns from research and development.¹⁸ Studies have shown that absent patent protection, only 40% of drugs in use today would have been developed. This is in comparison with the 86% of inventions across all industries which would have been produced without such protection.¹⁹ The reason for this anomaly is two-fold; research and development costs involved with bringing a drug to the market are huge whereas the actual production costs involved are insignificant. Consequently, in the absence of patent protection, generic drug companies would produce

¹⁴ *Ibid.*, cl 10.

¹⁵ *Ibid.*, cl 13(a).

¹⁶ L Bently and B Sherman, *Intellectual Property Law* (3rd ed., Oxford University Press, 2009) 365.

¹⁷ P Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (4th ed., Oxford University Press, 2004) 401.

¹⁸ G Dutfield, *Intellectual Property Rights and the Life Sciences Industry* (Ashgate Publishing Limited, 2003) 108.

¹⁹ E Mansfield, “Patents and Innovation: An Empirical Study” (1986) 32 *Management Science* 173, 175.

generic pharmaceuticals and market them for a fraction over the marginal production cost. In doing so, innovator drug companies would have no period in which to recoup sunk costs. As the situation stands, generic companies typically enter the market the day after a patent term expires.

The large research and development investments required are not only directed towards discovering new products, but also towards attaining regulatory approval. The most frequently cited statistics regarding the cost of pharmaceutical product development places the cost of bringing a drug to the market at US\$802 million (in 2000 dollars).²⁰ A sizeable proportion of this sum funds the clinical trial phase required to ensure efficacy and safety of drugs. Of every 5000 medicines tested, only one is eventually approved for patient use.²¹ Further studies show that it typically takes ten to fifteen years from drug discovery to regulatory approval.²² However a patent application must be filed at the drug discovery phase in order to preserve rights under the 'first to file' system in New Zealand. The 20 year patent term commences on the date the complete specification is filed in support of the application. Consequently, by the time the product has gained market approval, much of the 20 year monopoly may have elapsed.²³

²⁰ J DiMasi, R Hansen and H Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs" (2003) 22 *Journal of Health Economics* 151, 180. However some studies claim this cost is as great as \$2 billion (see C Adams and V Brantner, "Estimating The Cost Of New Drug Development: Is It Really \$802 Million?" (2006) 25 *Health Affairs* 420). Others have questioned the methodology of this study and suggest the true cost is only a fraction of US\$802 million (see Public Citizen, "Tufts Drug Study Sample Is Skewed; True Figure of R&D Costs Likely Is 75 Percent Lower" 4 December 2001, available at <http://www.citizen.org/pressroom/print_release.cfm?ID=954> last accessed 6/10/09).

²¹ Tufts Center for the Study of Drug Development, "Backgrounder: How New Drugs Move through the Development and Approval Process" 1 November 2001, available at <<http://csdd.tufts.edu/newsevents/recentnews.asp?newsid=4>> last accessed 6/10/09.

²² *Ibid.*

²³ Dutfield, above n 18, p120. However many patent systems provide patent term extensions to compensate for regulatory delays. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (usually referred to as the Hatch-Waxman Act) directly provides up to a five year extension. In the EU, Supplementary Protection Certificates indirectly compensate for regulatory delay however these are more limited in scope than the equivalent United States protection.

This provides some explanation for the pharmaceutical industry's endeavour to maximise the duration and scope of patents which attach to their 'blockbuster' drugs.²⁴ The term 'evergreening' is often used to describe the various strategies employed by the industry in achieving this goal.²⁵ A key element of evergreening is to file secondary patents, such as Swiss-type claims, to keep generics off the market.²⁶

1.3 The 'methods of medical treatment of human beings' exclusion from patentability

Patenting methods of medical treatment is a complicated issue as it concerns the interface between medical and patent law. The differing rationales behind these two areas of law has led to much debate over the years, particularly as to whether, and if so how, intellectual property in this area ought to be protected.

The exclusion from patentability of methods of medical treatment, which exists in a number of countries, is based on the premise that doctors must be free to treat their patients as they see fit. The exclusion ensures that the discretion of practitioners is not fettered. However such a prohibition leads to concern over innovation in this field as patent protection is essential for maintaining the impetus for innovation. Nowhere is this more true than in the field of pharmaceuticals. Although new pharmaceuticals attract patent protection by way of product claims, new treatment regimes using known drugs constitute methods of medical treatment. Without the promise of a period of market

²⁴ A 'blockbuster' drug is a drug with an annual global revenue of at least \$1 billion (for a review, see D Cutler, "The Demise of the Blockbuster?" (2007) 356 *New England Journal of Medicine* 1292).

²⁵ Dutfield, above n 18, p 109. An alternative description of these strategies is 'life cycle management strategies'.

²⁶ For a review of possible secondary patents, see M Burdon and K Sloper, "The art of using secondary patents to improve protection" (2003) 3 *International Journal of Medical Marketing* 226.

exclusivity, substantial research and development costs would preclude development of new treatment regimes.

(a) The international context

Article 27(3)(a) of the TRIPS Agreement permits contracting states to exclude from patentability ‘diagnostic, therapeutic and surgical methods for the treatment of humans and animals’. More than 80 countries currently prohibit medical method patents, including countries in the European Union (EU), Asia, Africa, North America and South America.²⁷ Notable exceptions include the United States and Australia.

Precedents dating back to 1914 have confirmed methods of medical treatment are not patentable in the United Kingdom (UK).²⁸ The practice of the UK Patent Office was confirmed by the codification of this exclusion in section 4 of the Patents Act 1977.²⁹ The exclusion is now found in section 4A of the Patents Act 1977 following recent amendments.³⁰

Patent law in the EU is dictated by the European Patent Convention (the EPC). Article 52(4) of the EPC 1973 expressly excluded methods of medical treatment from patentability.³¹ National laws of individual countries provide for this in differing ways.

²⁷ O Mitnovetski and D Nicol “Are patents for methods of medical treatment contrary to the ordre public and morality or “generally inconvenient”?” (2004) 30 Journal of Medical Ethics 470.

²⁸ *Re C & W’s Application* (1914) 31 RPC 235.

²⁹ Patents Act 1977, s4(2) provided (prior to amendments in 2004):

An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

³⁰ *Ibid.*, s4A(1) provides:

A patent shall not be granted for the invention of—

(a) a method of treatment of the human or animal body by surgery or therapy, or

(b) a method of diagnosis practised on the human or animal body.

³¹ Article 52(4) EPC 1973 provides:

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are

The UK, Germany and France, for example, have incorporated provisions affirming such methods are not industrially applicable. Sweden, Italy and Denmark have declared such methods to be non-inventions. The Swiss provisions exclude them simply as legal exceptions to patentability.³² The EPC 1973 has since been replaced by the EPC 2000. Under the new Convention, this exclusion is included as Article 53(c).³³

Methods of medical treatment have been considered patentable in the United States since 1954.³⁴ In 1998, following public outcry regarding the enforcement of a medical process patent by an ophthalmologist,³⁵ a bill was introduced which proposed to ban method of medical treatment patents. A compromise position was finally reached which focused on remedies available rather than changing the scope of patentability. The solution came in the form of a new subsection which grants medical practitioners immunity from liability

susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

³² Mitnovetski and Nicol, above n 27, p 471.

The relevant sections of national laws are listed below:

UK: Patents Act 1977, s4(2).

Germany: Patent Law of 16 December 1980 (as last amended by Laws of July 16 and 6 August 1998), s5(2). English version: <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=1035> last accessed 6/10/09.

France: Law No. 92-597 of 1 July 1992, on the Intellectual Property Code (Legislative Part) (as last amended by Law No. 96-1106 of 18 December 1996), article L611-16. English version: <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=1613> last accessed 6/10/09.

Sweden: Patents Act (Act No. 837 of 1967) (as last amended by Acts No. 1406 of 1993), s1. English version: <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=3606> last accessed 6/10/09.

Italy: Law on Patents for Inventions, Royal Decree No. 1127 of 29 June 1939 (as last amended by Legislative Decree No. 198 of 19 March 1996), article 12. English version: <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=2566> last accessed 6/10/09.

Denmark: The Consolidated Patents Act No. 366 of 9 June 1998 (as amended by Act No. 412 of 31 May 2000), s1(3). English version: <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=1176> last accessed 6/10/09.

Switzerland: Federal Law on Patents for Inventions (LBI) of 25 June 1954 (as amended on 24 March 1995), article 2. English version: <http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=656> last accessed 6/10/09.

³³ Article 53(c) EPC 2000 provides:

European patents shall not be granted in respect of:

- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

It is also of note that prior to the enactment of the EPC 2000, methods of medical treatment were excluded from patentability on the basis that they were not capable of industrial application. Under the EPC 2000, these methods are *directly* excluded from patentability.

³⁴ *Ex parte Scherer* 103 USPQ 107 (Pat. Off. Bd. App. 1954) overruled *Ex parte Brinkerhoff* 24 Commr's MS Decisions 349 (1883).

³⁵ *Pallin v Singer and Hitchcock Associates of Randall* 36 USPQ 2d 1050 (D Vt 1995).

for the “performance of a medical activity”.³⁶ Of note, however, is that ‘medical activity’ does not include the use of patented drugs or equipment, patented uses of drugs, nor biotechnological processes.³⁷

The Australian law was founded upon the English patent system, and methods of medical treatment were excluded for many years. However Australian law has recently departed from its predecessor. The Patent Commissioner has for some time accepted applications for processes for human treatment. This practice was upheld by a majority of the Full Court of the Federal Court of Australia in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*,³⁸ which ruled that methods of medical treatment were patentable in Australia. This stance was confirmed by the Full Court in *Bristol Myers Squibb Co v F H Faulding & Co Ltd*.³⁹ The law concerning methods of medical treatment in Australia is therefore similar to that in the United States, except that there is no equivalent immunity from liability for medical practitioners.

(b) The patent status of methods of medical treatment in New Zealand

The definition of ‘invention’ in the Patents Act 1953⁴⁰ includes no specific exclusion of methods of medical treatment from patentability. New Zealand has rejected such claims however, based primarily on the ‘generally inconvenient’ public policy proviso to section 6 of the Statute of Monopolies.⁴¹

³⁶ 35 USC 287(c)(1) (Supp. IV 1998).

³⁷ *Ibid.*, 287(c)(2)(A).

³⁸ (1994) 28 IPR 383.

³⁹ (1998) 41 IPR 467.

⁴⁰ Patents Act 1953, s2(1) provides:

‘Invention’ means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention.

⁴¹ Section 6 of the Statute of Monopolies provides:

VI. Provided also, and be it declared and enacted, that any declaration before mentioned shall not extend to any letters 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 manner of new manufactures within this Realm, to the true and first inventor and inventors of such manufactures, which others at the time of

Exclusion from patentability of claims directed to methods of medical treatment was approved by the Court of Appeal in the landmark decision of *Wellcome Foundation Ltd v Commissioner of Patents*⁴² (*Wellcome*). Two justifications for this exclusion were suggested. Firstly, all judgments noted that the ‘generally inconvenient’ proviso to section 6 of the Statute of Monopolies had been incorporated in the definition of ‘invention’ in the Patents Act 1953⁴³ and that patenting methods of medical treatment was objectionable on moral grounds because it restricted the ability of medical practitioners to use any available means of treating illness. Cooke J gave a further economic justification for the exclusion of methods of medical treatment from patentability. New Zealand is heavily dependent on overseas manufacturers of pharmaceuticals. Cooke J held that the incentives provided by patent protection for methods of medical treatment must be weighed against increased costs of importing or manufacturing drugs.⁴⁴

The ban on patenting methods of medical treatment was affirmed by the Court of Appeal in *Pharmaceutical Management Agency Ltd v Commissioner of Patents*⁴⁵ (*Pharmac*). The Court suggested that this prohibition may be illogical; nonetheless it was noted that any change ought to come from Parliament.⁴⁶ Contrary to *Wellcome*, a different legal justification was provided for the exclusion. No longer could the exclusion be based on the ‘generally inconvenient’ proviso to section 6 of the Statute of Monopolies; rather, the Court held that patenting methods of medical treatment would be contrary to morality and therefore excluded under section 17(1) of the Patents Act 1953.⁴⁷

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 of commodities at home, or hurt of trade, or generally inconvenient:..

⁴² [1983] NZLR 385 (CA).

⁴³ *Ibid.*, p 387.

⁴⁴ *Ibid.*, p 391.

⁴⁵ [2000] 2 NZLR 529 (CA).

⁴⁶ *Ibid.*, para 27.

⁴⁷ *Ibid.*, para 26.

The Court of Appeal in *Pfizer Inc v Commissioner of Patents*⁴⁸ (*Pfizer*) affirmed both the decision and the reasoning in *Wellcome*. The Court held that the ‘generally inconvenient’ proviso to section 6 of the Statute of Monopolies is included in the definition of invention,⁴⁹ and that the ban on patenting methods of treatment is justified by that provision.⁵⁰

The Patents Bill 2008 expressly excludes methods of treatment from patentability.⁵¹ Such an amendment would remove any remaining uncertainty concerning this troublesome issue. The following chapter considers a form of claim known as a ‘Swiss-type claim’ which has been devised to evade the methods of medical treatment exclusion with respect to pharmaceuticals.

⁴⁸ [2005] NZLR 362 (CA).

⁴⁹ *Ibid.*, para 52.

⁵⁰ *Ibid.*, para 52.

⁵¹ Patents Bill, above n 4, cl 15. Clause 15 provides:

Clause 15(2): An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.

II. THE PRESENT: THE EROSION OF THE METHODS OF MEDICAL TREATMENT EXCLUSION BY SWISS-TYPE CLAIMS

2.1 The evolution of Swiss-type claims

The type of research undertaken by the pharmaceutical industry has experienced a change in direction over the past 40 years. This change in focus was the result of a realisation that in this field, the possibility of discovering new drug compounds was decreasing.⁵² Consequently, researchers began to concentrate on the discovery of new uses for known substances; that is, where a known substance already used in the treatment of some medical condition is subsequently found to have a secondary medical use. This trend has continued to gain momentum as the medical product pipeline has progressively dried up.⁵³ Despite a large increase in research and development, the number of new chemical entities reaching the market has been in steady decline.⁵⁴ The majority of new treatments are simply new uses of already known drugs.

The problem researchers were initially confronted with was that ‘second use’ drugs were unpatentable in countries with the medical method exclusion. Product claims provide no protection as patent laws refuse to recognise ‘novelty of purpose’ as a proper basis for granting a product patent.⁵⁵ As the substance itself is already known, it cannot be patented. Use claims traditionally were also inadequate; although the second use was

⁵² Bently and Sherman, above n 16, p 478.

⁵³ B Evans, D Flockhart and E Meslin, “Creating incentives for genomic research to improve targeting of therapies” (2004) 10 *Nature Medicine* 1289.

⁵⁴ A review of products licensed by the FDA and EMEA (the respective United States and EU licensing authorities) in 2002 showed that only 18 and 13 new molecular entities were approved by the regulators respectively (S Frank and A Smith, “New drug approvals for 2002” (2003) 2 *Nature Reviews Drug Discovery* 95; cited in A Hedgecoe, *The Politics of Personalised Medicine* (Cambridge University Press, 2004) 13).

⁵⁵ Bently and Sherman, above n 16, p 479.

novel, the methods of medical treatment exclusion prevented the patenting of the new use of a pharmaceutical.⁵⁶

A new form of claim was devised which avoids claiming either the method of treatment or the product itself. Rather, what is claimed is the use of the known compound in the *manufacture of the medicament for the new use*.⁵⁷ These claims are known as ‘Swiss-type claims’ as they were first proposed by the Swiss Federal Intellectual Property Office.⁵⁸

‘Swiss-type claims’ evade the methods of medical treatment exclusion. The merit of these claims is that drug companies are provided with an incentive to continue research into new uses of known drugs, without the countervailing disadvantage of interfering with doctors’ discretion. Medical practitioners remain free to use the medicament for the new purpose without fear of infringement, yet the patentee has the ability to restrain the *manufacture* of the medicament for that purpose.⁵⁹ The moral objection to patenting methods of medical treatment is avoided.

Critics argue, however, that these claims are simply disguised claims to methods of treatment. Considering substance over form, Swiss-type claims should be refused. Consequently, there has been much debate regarding the acceptability of these claims. Furthermore, Swiss-type claims are subject to a significant legal objection. It is a principle of patent law that novelty must derive from the subject-matter of the patent claim, not some related use. These claims concern use of a substance in the manufacture of a medicament. Therefore novelty ought to reside in *that* specific use, such as use in a new

⁵⁶ *Ibid.*, p 479.

⁵⁷ The orthodox form of a Swiss-type claim is ‘the use of [known compound X] for the manufacture of a medicament for the treatment of [new therapeutic use]’ (IPONZ Practice Guidelines for the examination of Swiss-type claims (updated 8 April 2009), available at < <http://www.iponz.govt.nz/cms/patents/patent-topic-guidelines/2004-business-updates/guidelines-for-the-examination-of-swiss-type-claims?searchterm=swiss> > last accessed 6/10/09).

⁵⁸ Statement of practice of the Swiss Federal Intellectual Property Office [1984] OJ EPO 581.

⁵⁹ *Pharmac*, above n 45, para 17.

manufacturing process.⁶⁰ But, of course, Swiss-type claims normally disclose no novelty in the manufacture of the drug.

The evolution of Swiss-type claims will be considered below followed by discussion of the extension of these claims.

(a) Swiss-type claims in the European Union

(i) The European Patent Convention 1973

Article 54(5) of the European Patent Convention 1973 was introduced following the insistence by the pharmaceutical industry that patent protection was required for new uses of known drugs. Article 54(5) stated that any known substance or composition for use in a method of medical treatment is not excluded from patentability, provided that “its use for any method referred to in [Article 52(4)] is not comprised in the state of the art.”

There was some controversy between contracting states concerning the meaning of Article 54(5). It was clear that Article 54(5) extended patent protection to first pharmaceutical use claims; that is, where a composition existed but had no known therapeutic use, discovery that this substance may be used as a pharmaceutical was patentable. Whether this could be further extended to protect second and subsequent therapeutic uses however, was an open question.

The majority of contracting states were in favour of a restrictive interpretation, whereby only the first medical use of known products could be patented;⁶¹ claims for second or

⁶⁰ D Armstrong “The Arguments of Law, Policy and Practice Against Swiss-type Patent Claims” (2001) 32 Victoria University of Wellington Law Review 201, 219.

subsequent medical uses were thought to lack novelty and were unpatentable for that reason. The basis for this restrictive interpretation was the inclusion in Article 54(5) of the word “any”. Arguably, this prevented second medical use claims because by the time the second use was discovered, the first medical use was known and the second use claim would infringe the proviso that the drug be unknown for use in *any* method of medical treatment.⁶² The pharmaceutical industry supported a much wider interpretation that would permit second use claims.⁶³

Initially, the European Patent Office (EPO) interpreted Article 54(5) literally and refused to accept the wider construction.⁶⁴ The national courts of Germany took a different approach. In *Hydropyridine*⁶⁵ the German Federal Court of Justice held that although section 5(2) of the German Patent Act 1968 is worded identically to Article 52(4) of the EPC 1973, it did not preclude direct claims for new uses of known drugs. The same application was then filed in the EPO where it was rejected, appealed and then referred to the Enlarged Board of Appeal. This appeal, along with seven other applications, was determined in the landmark *EISAI/Second Medical Indication*⁶⁶ decision (*Eisai*).

(ii) *EISAI/Second Medical Indication*

The Enlarged Board of Appeal (EBA) was faced with the task of deciding whether a claim for the new use of a known drug was patentable, given the prohibition on methods of medical treatment in Article 52(4) of the EPC 1973. In considering this issue, it took note of the statement of practice issued by the Swiss Federal Intellectual Property Office in

⁶¹ E Ventose, “Patent Protection for Second and Further Medical Uses Under the European Patent Convention” (2009) 6 SCRIPTed 57, 62, available at <<http://www.law.ed.ac.uk/ahrc/script-ed/vol6-1/ventose.asp>> last accessed 6/10/09.

⁶² Armstrong, above n 60, p 210.

⁶³ Ventose, above n 61, p 62.

⁶⁴ T128/82 *HOFFMAN-LA ROCHE/Pyrrrolidine derivatives* [1984] OJ EPO 164.

⁶⁵ *Hydropyridine* X ZB 4/83 [1984] OJ EPO 26 (German Federal Court of Justice).

⁶⁶ G5/83 *EISAI/Second medical indication* [1985] OJ EPO 64.

which it was held that although ‘use’ claims of the German type breached the medical method exclusion, claims in the form ‘use of compound X for the preparation of an agent for the treatment of disease Y’ were acceptable.⁶⁷

After some consideration, the EBA held that direct second use claims (such as those in *Hydropyridine*) were method of medical treatment claims and therefore unpatentable, but the indirect Swiss form of claim was accepted. Such claims were held to be “justifiable by analogy”⁶⁸ with the first medical uses permitted by Article 54(5), so that novelty could be derived from the new use. Article 54(5) was thus extended to protect second and subsequent medical uses. Although the EBA recognised that novelty did not reside in the subject-matter of these claims, this limitation was not considered to be fatal.⁶⁹

(iii) The European Patent Convention 2000

Any reservations regarding the patentability of second and subsequent medical use claims have been allayed following the enactment of the EPC 2000 which came into force in 2007.⁷⁰ Article 54(5) remains as Article 54(4). A new Article 54(5) essentially codified the case law from the EPO regarding second and subsequent use claims.⁷¹ Under this provision, applicants can *directly* claim second and subsequent medical uses of known compositions in the form ‘substance X for curing disease Y’.⁷² The Swiss form of claim is

⁶⁷ Swiss Federal Intellectual Property Office, above n 58.

⁶⁸ *Eisai*, above n 66, para 21.

⁶⁹ *Eisai*, above n 66, para 18 (discussed in *Ventose*, above n 61, p 65).

⁷⁰ European Patent Convention 2000 (in force as of 13 December 2007).

⁷¹ Article 54 EPC 2000 provides:

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

⁷² Guidelines for Examination in the European Patent Office, Part C, IV-10, April 2009, available at <[http://documents.epo.org/projects/babylon/eponet.nsf/0/1afc30805e91d074c125758a0051718a/\\$file/guidelines_2009_complete_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/1afc30805e91d074c125758a0051718a/$file/guidelines_2009_complete_en.pdf)> last accessed 6/10/09.

no longer required, however will still be accepted.⁷³ Whether insertion of the new Article 54(5) will change the law in any significant way will be clarified when the EBA hands down its judgment on the questions proposed by the Technical Board of Appeal (TBA) in *Kos Life Sciences*.⁷⁴

The form of claim permitted by Article 54(5) of the EPC 2000 is flawed. The direct form of claim resolves the issue of novelty inherent in Swiss-type claims, yet it is difficult to reconcile with the methods of medical treatment exclusion. By claiming use of the known compound in treating the new disease, novelty resides in the subject-matter of the claim. But the same issues arise as existed before the introduction of Swiss-type claims; if the subject-matter of the claim is use of a pharmaceutical in therapy, the claim is directed to a method of medical treatment. These direct claims have the potential to severely restrict the discretion of practitioners, as they do not even attempt to limit their scope to manufacturers. Although unlikely to be enforced against a practitioner, this new provision does leave that possibility open. Therefore the effect of this new form of claim is simply to legitimise what would otherwise be a clear breach of the methods of medical treatment exclusion. This exclusion exists for a reason, that being to ensure the discretion of medical practitioners is not fettered. Although claims under Article 54(5) of the EPC 2000 are now considered legal, the same moral objections apply.

(b) Swiss-type claims in the United Kingdom

Although the relevant legislation in the UK reflects the EPC 1973,⁷⁵ UK courts are not bound to follow EU decisions. There was initial concern that national UK courts would

⁷³ It is recommended that patent applications include both claims in indirect Swiss form and the newly accepted direct form (see Guidelines for Examination in the European Patent Office, above n 72, Part C IV-10).

⁷⁴ T 1319/04 *KOS LIFE SCIENCES/Dosage regimen* [2009] OJ EPO 36; discussed below at para 2.3(a)(i)(2).

⁷⁵ Articles 52(4) and 54(5) EPC 1973 were reproduced in sections 4(2) and 2(6) respectively of the Patents Act 1977 (UK).

deem Swiss-type claims to be invalid. *Wyeth's and Schering's Applications*⁷⁶ was an appeal against two separate decisions of the UK Patent Office. Although initially rejected by the Hearing Officer, the UK Patent Court affirmed the reasoning from *Eisai* and granted a patent with claims of the Swiss type. Despite recognising the novelty issue, the desire to achieve conformity with European patent law was of greater significance.⁷⁷

Second use claims in the Swiss form continued to be widely accepted in the UK following *Wyeth and Schering's Applications* until *Bristol-Myers Squibb Company v Baker Norton Pharmaceuticals Inc*⁷⁸ (*BMS*). This case concerned a dosage regime where novelty resided in the new infusion period. Both Jacob J at first instance and the appellate court justices found such regimes to be obvious and as such, unpatentable. However in doing so, Swiss-type claims in their orthodox form were considered. At first instance, Jacob J questioned the reasoning in support of Swiss-type claims, yet he reluctantly concluded that in order to achieve conformity within the EU, such claims would be acceptable.⁷⁹ The Court of Appeal reached the same decision.

Following enactment of the EPC 2000, amendments were made to the Patents Act 1977 in order to bring the UK patent system into line with the revised EPC. These amendments came into force in December 2007. A new section 4A(3) was inserted which corresponds to Article 54(4) of the EPC 2000. This provision permits patent protection for the first medical use of a known substance or composition and has the same effect as the previous section 2(6) of the Patents Act 1977.⁸⁰ A new section 4A(4) was inserted which mirrors Art 54(5) of the EPC 2000. It enables patent protection to be obtained for second and subsequent uses of a known substance by direct claim.⁸¹ Although it is now possible to

⁷⁶ [1985] RPC 545 (Pat. Ct.).

⁷⁷ *Ibid.*, p 565.

⁷⁸ [1999] RPC 253 (Pat. Ct.); [2001] RPC 1 (CA).

⁷⁹ *BMS* (Pat. Ct.), above n 78, p 272.

⁸⁰ Explanatory Notes to the Patents Act 2004, para 20.

⁸¹ *Ibid.*, para 22. A direct form of claim is as follows: "(Substance X) for use in the treatment of (medical condition Y)".

directly claim the new use of the known substance, the Swiss form of claim may still be used.⁸² It has been emphasised that there will be no differences between the scope of protection afforded under Swiss-type claims and the new direct form of claim;⁸³ confirmation of this is expected in the pending decision of the EBA in *Kos Life Sciences*.⁸⁴ The UK Court of Appeal, in its most recent case concerning Swiss-type claims,⁸⁵ has extended the time for leave to appeal to the House of Lords until 28 days after the EBA gives its decision in *Kos Life Sciences*.

(c) Acceptance of Swiss-type claims in New Zealand

Swiss-type claims were first considered by IPONZ in 1990. The Commissioner of Patents issued a Practice Note stating that claims for the use of known compounds, in the manufacture of a medicament for a new use, were prohibited. The justification provided was that the manufactured medicament is not novel unless it is materially different from previous compositions; the fact that it was intended for use in treating a different medical condition was held to be irrelevant.⁸⁶

This remained the status quo until 1997 when a second Practice Note was issued which stated such claims would now be accepted. The justification given for this sudden change in practice was the fact that Swiss-type claims were widely accepted overseas and so ought to be accepted in New Zealand.⁸⁷

⁸² Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office (August 2008), para 8, available at <<http://www.ipo.gov.uk/medicalguidelines.pdf>> last accessed 6/10/09.

⁸³ Explanatory Notes, above n 80, para 19.

⁸⁴ *Kos Life Sciences*, above n 74; discussed below at para 2.3(a)(i)(2).

⁸⁵ *Actavis v Merck* [2008] EWCA Civ 444.

⁸⁶ This practice note was issued on 22 March 1990 and is reproduced in *Pharmac*, above n 45, para 2.

⁸⁷ This practice note was issued on 7 July 1997 and is reproduced in *Pharmac*, above n 45, para 3.

This Practice Note was the subject of judicial review proceedings brought by the Pharmaceutical Management Agency. The High Court granted a declaration upholding the terms of the Practice Note. The Court of Appeal in *Pharmaceutical Management Agency Ltd v The Commissioner of Patents*⁸⁸ (*Pharmac*) affirmed the legality of Swiss-type claims. Gault J, delivering the judgment of the Court, held that there can be invention and novelty in the discovery of unrecognised properties of known pharmaceuticals.⁸⁹ Accordingly, there is an obligation to make patent protection available.⁹⁰ It was reasoned that this new use constituted the inventive subject-matter and novelty, but since this use cannot be captured with a method claim, designation of purpose will be sufficient.⁹¹ Furthermore, the Court was of the opinion that nothing in New Zealand's legislation or case law precludes reliance on a similar process of reasoning as that adopted in *Eisai*. Lack of counterparts to the relevant EPC provisions was not fatal as the reasoning in *Eisai* was not dictated by such provisions.⁹² Since the Court of Appeal's decision in *Pharmac*, claims in the Swiss form have been accepted in IPONZ.

There is no discussion of Swiss-type claims in the Patents Bill 2008, therefore by implication, Parliament approves of these claims. No equivalent to section 4A(4) of the Patents Act 1977 and Article 54(5) of the EPC 2000 is included in the Bill. Consequently IPONZ will continue to reject *direct* claims for the second or subsequent use of a known pharmaceutical, but accept claims in the Swiss form.

⁸⁸ *Pharmac*, above n 45.

⁸⁹ *Ibid.*, para 64.

⁹⁰ *Ibid.*, para 65.

⁹¹ *Ibid.*, para 65.

⁹² *Ibid.*, para 51.

2.2 The shortcomings of orthodox Swiss-type claims

Swiss-type claims have been devised to overcome two obstacles to patentability; the novelty requirement and the methods of medical treatment exclusion. As discussed, legal objections arise regarding these claims due to a lack of novelty. Although the use in treating the medical condition is new, novelty does not reside in the subject-matter of the claim.

It has been asserted that Swiss-type claims erode the methods of medical treatment exclusion. Although the use of an active ingredient for the manufacture of a medicament is directed to the actions of the manufacturer, and practitioners cannot infringe Swiss-type claims, the new use in treating a disease is included in the claim. An issue arises as to whether, in practical terms, these claims thwart the purpose of the methods of medical treatment exclusion and fetter the discretion of practitioners.⁹³ The choice of appropriate drug to prescribe is traditionally included in the role of the practitioner in treating his patient. Although the claim is directed to the manufacturer, the patent protection conferred by Swiss-type claims will result in monopoly prices which limit availability of drugs. However economic considerations are no longer a justification for the methods of medical treatment exclusion following *Pharmac*, therefore such concerns are irrelevant.

The practical repercussions of lack of patent protection for second use claims are debatable. Second medical use claims may be merely discoveries, which are unpatentable. Even if conscious effort is required in the development of new uses, this is likely to be much less onerous than the research required in developing new compounds. Therefore Swiss-type claims may be unnecessary, and lack of protection for second uses may not

⁹³ Gault J has stated that the purpose of the exclusion is to ensure that the discretion of medical practitioners is not fettered (*Pharmac*, above n 45, para 29).

stifle research.⁹⁴ In fact, perhaps removal of the Swiss form of claim would focus the attention of drug companies on discovering new substances.

Given the shortcomings of Swiss-type claims, a number of alternative options are considered. The methods of medical treatment exception could simply be removed. Swiss-type claims would consequently be redundant as second medical uses could be protected by way of method claims. There would be no issues concerning the novelty of such claims, and similarly they would not be excluded from patentability. The only issue would concern the inventiveness of the subject-matter. However, removing the prohibition on method of treatment claims would not only affect the patentability of second uses of pharmaceuticals, but also surgical and therapeutic treatment methods. In order to protect practitioners from infringement proceedings, legislation should provide that medical practitioners who use a patented method without the patent owner's permission would be exempt from infringement proceedings. Such an approach would have the advantage of focusing attention on the requirements of inventiveness and novelty.

The Court of Appeal in *Pharmac* foreshadowed the possibility of removing the methods of medical treatment exclusion. It indicated that a more logical approach, leading to the same result, would be to permit patents directed to methods of medical treatment but to require from the patentee a disclaimer of any right to sue the practitioner.⁹⁵ This idea was explored in *Pfizer* by counsel for the appellant who said his client would be prepared to disclaim any ability to sue practitioners. Although the Court ultimately rejected this argument, this appears to have been based on inadequacies in the form of the disclaimer proposed. However given its inclusion in the Patents Bill 2008, abandonment of the methods of medical treatment exclusion is unlikely.

⁹⁴ Armstrong, above n 60, p 237.

⁹⁵ *Pharmac*, above n 45, para 65.

Another option would be to follow the approach adopted in Article 54(5) of the EPC 2000 and section 4A(4) of the Patents Act 1977, and expressly endorse second medical use claims in their direct form. As the EU recognised, the legislature needs to make the judgment call as to whether Swiss-type claims should be permitted, and more importantly, precisely what their scope should be. However the acceptance of direct claims is riddled with problems as complex as those attaching to Swiss-type claims. Although direct claims would avoid the issues of novelty which arise with Swiss-type claims, such claims cannot be reconciled with the exclusions of methods of medical treatment.

Swiss-type claims are a necessary evil. Although such claims increase the cost of drugs by providing the patentee with exclusive rights for 20 years, without such protection development would not occur. Given the wide acceptance of Swiss-type claims both in New Zealand and internationally, the continued acceptance of these claims is inevitable.

2.3 Extending the reach of Swiss-type claims

In the past 20 years, the boundaries of Swiss-type claims have been continuously stretched in order to provide patent protection for discoveries other than new medical indications. The question examiners and the courts have been confronted with is whether there is any difference between a *new* use of a *known* pharmaceutical (orthodox Swiss-type claim), and a *known* use of a *known* pharmaceutical administered in a *new* way or to a *new* patient group (extended Swiss-type claims). Such claims will be referred to as 'extended Swiss-type claims' and provide an example of a further 'evergreening' technique employed by the pharmaceutical industry.

Whether the merits of orthodox Swiss-type claims remain when these claims are extended is a point of contention. This chapter will consider whether Swiss-type claims remain economically and socially justifiable in their extended form. At some point of extension, providing patent protection must be considered counterproductive.

In order for patent protection to be conferred, it has to be established that the subject-matter is novel, involves an inventive step, and is not directed to a method of medical treatment. The decisions discussed below appear to place different weight on each of these requirements.

(a) The European Union

(i) New method, time, frequency or dosage of administration

A number of cases considered whether claims concerning new dosage regimes or methods of administration were in breach of Article 52(4) of the EPC 1973. Initially, claims were accepted in which the distinguishing feature was the mode of administration.⁹⁶ However, where the novelty and inventive step resided in a new dosage regime, it was held that determination of dosage to comply with the specific needs of a patient required the exercise by the medical practitioner of his professional skill.⁹⁷ Such activities were typical of the non-commercial and non-industrial medical activities which Article 52(4) of the EPC 1973 intended to be free from restraint. The Board considered such claims to be an attempt to obtain protection for a methods of therapeutic treatment and therefore unpatentable.⁹⁸

⁹⁶ T 0051/93 *SERONO/HCG* (Unpublished) 8 June 1994.

⁹⁷ T 0056/97 *EURO-CELTQUES/Thiazide diuretics* (Unpublished) 30 August 2001; T 0317/95 *PROCTER & GAMBLE/Gastrointestinal compositions* (Unpublished) 26 February 1999.

⁹⁸ *Procter & Gamble*, above n 97.

Although such method of medical treatment objections have been rejected regarding orthodox Swiss-type claims, these considerations are of more significance concerning dosage regimes, due to the nature of the new use. New uses of drugs have traditionally been determined by drug companies, and blindly followed by practitioners. Determining the new use of a drug does not take place on an individual patient-doctor level. Rather, a broad claim is made that drug X works to treat condition Y. In contrast, determinations of dosage regimes have typically been made by practitioners, with respect to the individual patients concerned. Pharmaceuticals have varying efficacies and toxicities in individuals, and many drugs therefore require the specific tapering of dosage and timing of administration in order to benefit from the drug. For this reason, many objections were made to Swiss-type claims which incorporated new dosage regimes.

These objections have been rejected. Although it is accepted that dosage regimes do fall within activities typical of a practitioner, Swiss-type claims are directed solely to the manufacture of a medicament and therefore do not affect the discretion of practitioners to administer drugs as they see fit. Despite this conclusion, the same cannot be said of the new direct claims provided for under Article 54(5) of the EPC 2000 and section 4A(4) of the Patents Act 1977. These provisions permit new dosage regimes to be directly claimed, and therefore, although extremely unlikely in practice, such claims are in theory enforceable against practitioners.

1. *GENENTECH/Method of administration of IGF-1*⁹⁹

The decision of the TBA in *Genentech* recognised that a pure dosage regime was patentable. This case concerned a new dosage regime for the administration of IGF-1 in the preparation of a medicament for treating chronic renal failure. The new regime was distinguished by an intermittent course of treatment. Although initially refused on the

⁹⁹ T 1020/03 *GENENTECH/Method of administration of IGF-1* [2007] OJ EPO 204.

basis that determination of a treatment schedule is part of the typical activities of medical practitioners, the TBA accepted the claim on appeal. The reasoning in a number of earlier decisions was considered to be conflicting with *Eisai*. It was rationalised that the logic of *Eisai* applies equally to any use of a known composition for a new and inventive treatment.¹⁰⁰ Therefore the claims under review avoided the prohibition in Article 52(4) of the EPC 1973 and were directed to potentially patentable subject-matter.

Following this decision, the EPO have accepted that claims to new dosage regimes drafted in the Swiss form avoid the methods of medical treatment prohibition.¹⁰¹ Novelty and inventive step may reside in the intended method of treatment for which the medicament was manufactured.¹⁰² However the majority of cases concerning new dosage regimes or modes of administration will fail for lack of inventive step.

2. *KOS LIFE SCIENCES/Dosage regimen*¹⁰³

The decision in *Genentech* has been questioned following the EPC 2000's entry into force. As discussed in paragraph 2.1(a)(iii), the EPC 2000 differs from the EPC 1973 in that it expressly provides for the patentability of the second medical use of a known substance or composition, by way of a direct claim. Whether introduction of the EPC 2000 will have any effect on the "settled view"¹⁰⁴ of the EPO regarding extended Swiss-type claims is yet to be seen.

¹⁰⁰ *Ibid.*, para 72.

¹⁰¹ T 0036/04 *UNIVERSITY OF TEXAS/DNA damaging agents* (Unpublished) 16 February 2006, T 0292/04 *EXOXEMIS/Haloperoxide* (Unpublished) 17 October 2005, T 0380/05 *PRAECIS/GnRH Antagonists* (Unpublished) 13 April 2006 and T 1074/06 *ARS/Infertility* (Unpublished) 9 August 2007; cited in *Actavis v Merck*, above n 85, para 39.

¹⁰² *University of Texas*, above n 101, para 3.

¹⁰³ *Kos Life Sciences*, above n 74.

¹⁰⁴ The Court of Appeal in *Actavis v Merck*, above n 85, held that the approach taken in *Genentech*, above n 99, represented the "settled view" of the EPO.

This was the question the TBA was faced with in *Kos Life Sciences*. The claims at issue regarded use of nicotinic acid for the manufacture of a sustained release medicament for use in the treatment, *once per day prior to sleep*, of hyperlipidaemia. They had been refused by the Examining Division on the basis that deciding upon a dosage regime is the activity of the medical practitioner, and therefore the claims were directed to a method of medical treatment.

The TBA considered prior case law, specifically indicating that it would apply *Genentech*. But, as *Kos Life Sciences* was the first case to be decided under Art 54(5) of the EPC 2000, the TBA considered that authoritative interpretation was required which only the Enlarged Board of Appeal could provide.¹⁰⁵ The TBA noted that this is an important point of law, and if such claims are to be excluded from patentability, then applicants need to know this for certain.¹⁰⁶

Therefore the Board referred a number of questions to the Enlarged Board of Appeal, asking for clarification as to whether claims, where the only novel feature of the treatment is a new and inventive dosage regime, could be patented under the EPC 2000. The following questions are to be considered by the EBA:¹⁰⁷

1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?
2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?
3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

¹⁰⁵ *Kos Life Sciences*, above n 74, para 5.1.

¹⁰⁶ *Ibid.*, para 5.2.

¹⁰⁷ *Ibid.*

A decision is still pending from the EBA, with oral proceedings scheduled to take place on 5 November 2009. The EBA's decision on this matter will no doubt have consequential effects in New Zealand.

(ii) New patient group

Swiss-type claims have been extended to inventions where novelty resides in the new patient group. The primary issue with these claims tends to be whether the subject-matter of such claims is novel. The majority of cases concerning new patient groups are little concerned with whether the claim infringes the methods of medical treatment exclusion.¹⁰⁸ The inventive step element is also rarely considered in depth in the following decisions. Whether a claim involves an inventive step tends to be one of fact, determined on a case by case basis.

1. *DUPHAR/Pigs II*¹⁰⁹

In *Duphar*, the TBA allowed claims that were directed to the application of a known vaccine to sero-positive pigs, where it was not previously known to be useful in that class of pigs. Although there was no new therapeutic application of the vaccine to a different ailment, novelty could nonetheless reside in the new class of pigs to be treated: sero-positive pigs that are maternally immune.¹¹⁰ The TBA was of the opinion that:¹¹¹

The question whether a new therapeutic use is in accordance with the decision GR 05/83 [*Eisai*] should not be answered exclusively on the basis of the ailment to be cured but also on the basis of the subject (in the present case the new group of pigs) to be treated.

¹⁰⁸ See, for example, T 1399/04 *Schering/Combination therapy HCV* (Unpublished) 25 October 2006, para 21.

¹⁰⁹ T 0019/86 *DUPHAR/Pigs II* [1989] OJ EPO 25.

¹¹⁰ *Ibid.*, para 11.

¹¹¹ *Ibid.*, para 8.

Critics have contended that this reasoning is dubious, as the *Eisai* principle demanded that the medical purpose be novel.¹¹²

2. *QUEEN'S UNIVERSITY KINGSTON/Controlling bleeding*¹¹³

The principle that novelty could reside in a new patient group was confirmed in *Queen's University Kingston*. Use of a composition to control bleeding in non-haemophilic mammals was not considered to be anticipated by its prior use in controlling bleeding in haemophilic mammals. In this case, the new patient group differed from the original patient group in their blood coagulation process, as the latter group differed in their genotype for an essential blood-clotting factor.

3. *MEDCO RESEARCH/Adrenaline*¹¹⁴

In *Medco Research*, the TBA affirmed *Duphar* but added two conditions that must be satisfied in order for a second use claim based on a new patient group to attract novelty. First, the new patient group must be clearly distinguishable (with respect to its physiological or pathological status) from the patient group treated in the prior art, and the two groups must not overlap. Secondly, the choice of the new group must not be arbitrary, which means that there must exist a functional relationship between the particular physiological or pathological status of this new group and the therapeutic effect obtained.¹¹⁵ This means the feature identifying the new group of patients must have a real impact on the result of the treatment.¹¹⁶

¹¹² Ventose, above n 61, p 71.

¹¹³ T 0893/90 *QUEEN'S UNIVERSITY KINGSTON/Controlling bleeding* (Unpublished) 22 July 1993.

¹¹⁴ T 0233/96 *MEDCO RESEARCH/Adrenaline* (Unpublished) 4 May 2000.

¹¹⁵ *Ibid.*, para 8.7

¹¹⁶ *Ibid.*

The claim in this case concerned the use of adenosine to detect vascular disease in patients who were unable to exercise adequately. After specifying the conditions, the TBA proceeded to find neither condition satisfied in the case before it. In relation to the first condition, the TBA concluded that the definition of new patient group, being ‘patients who are unable to exercise adequately’, was too vague and general.¹¹⁷ In respect of the second, the TBA asserted that there was no functional relationship between the incapability of a patient to exercise adequately and the pharmacological effect achieved by the administration of adenosine.¹¹⁸

4. *SCHERING/Combination therapy HCV*¹¹⁹

Despite initial acceptance, the EPO has since amended the *Medco Research* requirements. In *Schering*, the claim concerned a known treatment for hepatitis C virus (HCV) in the treatment of antiviral treatment naive patients infected with a high titre of the HCV-1 subtype.

The precise meaning and scope of the TBA’s decision in *Schering* is somewhat contentious. The Board disagreed with the interpretation in *Medco Research of Duphar* and *Queen’s University Kingston*. The TBA saw no basis for such a conclusion, which suggests that post *Schering*, neither requirement would be imposed. However the Board then went on to distinguish the claim before them from that in *Medco Research* on the basis that there was no functional relationship in *Medco Research* between the feature distinguishing the patient group and the pharmacological effect achieved. This was not so in the case before them, and for that reason alone the Board reasoned that the conclusion from *Medco Research* did not apply.¹²⁰

¹¹⁷ *Ibid.*, para 8.8.

¹¹⁸ *Ibid.*

¹¹⁹ *Schering*, above n 108.

¹²⁰ *Ibid.*, para 35.

Given the decision in *Schering*, it appears that the requirement that the new group not overlap with the group previously treated has been removed. This is the interpretation of *Schering* adopted by the UK Patent Office in their recent guidelines.¹²¹

It is more uncertain whether the second requirement from *Medco Research* has also been abandoned.¹²² Acknowledgement that this requirement is fulfilled suggests that it still exists. Indeed, there is no suggestion in the UK Patent Office Guidelines that *Schering* removed this requirement. In *Schering*, despite initially seeing no basis for this requirement, the TBA went on to distinguish the claims before them from those in *Medco Research*, based solely on the fact that such a functional relationship did exist in the case before them.

Interpretation of *Schering* in New Zealand has further complicated the status of the *Medco Requirements*.¹²³ Therefore the precise meaning of the TBA's decision in *Schering* remains uncertain.

(iii) New technical effect or mechanism of action

It is possible that applications relating to a known compound for the same therapeutic use, but claiming a different technical effect or mechanism of action, are acceptable by the EPO. Traditionally, claims directed to such applications have been routinely rejected due to a lack of novelty.¹²⁴ But recently, a claim regarding the new technical effect of a

¹²¹ Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office, above n 82, para 130.

[T]he EPO have held that the new patient group **can** overlap with, or be a subset of, the patients treated in the prior art.

¹²² This requirement is that choice of the group not be arbitrary, which means that a functional relationship must exist between the physiological or pathological status of this new group and the therapeutic effect obtained.

¹²³ *AstraZeneca AB's Application*, P24/2007, 3 September 2007, p 27; discussed below at para 2.3(c)(ii).

¹²⁴ T 0254/93 *ORTHO PHARMACEUTICAL/Prevention of skin atrophy* [1998] OJ EPO 285; T 0486/01 *GENENTECH/IGF-1*(Unpublished) 3 September 2003.

substance was accepted as being both novel and inventive.¹²⁵ This demonstrates acceptance by the EPO of a further extension of Swiss-type claims.

(b) The United Kingdom

(i) New method, time, frequency or dosage of administration

The issue of whether Swiss-type claims can be extended to permit patents for new dosage regimes has been the source of controversy in the UK. As in the EU, the issue in contention is whether such regimes are an excluded method of medical treatment. Initially, the Court of Appeal in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals*¹²⁶ (*BMS*) refused to accept dosage regimes as patentable subject matter. However earlier this year, the UK Court of Appeal departed from the *BMS* decision and in doing so, aligned UK practice with that of the EPO.¹²⁷

The claim in *BMS* regarded a new dosage regime for an anti-cancer drug.¹²⁸ The Court of Appeal held that such a claim was to a method of treatment, rather than a method of manufacture. Of particular note in coming to this decision was the fact that it was directed to actions taken by the doctor, rather than the manufacturer.¹²⁹ Furthermore, the claim was held to lack novelty as this cannot lie in the new method of use, but rather must lie in the new therapeutic purpose for which the substance is used.¹³⁰ Therefore not only was

¹²⁵ T 0509/04 *ALLERGAN/Cerebral Palsy* (Unpublished) 5 July 2005.

¹²⁶ *BMS*, above n 78.

¹²⁷ *Actavis v Merck*, above n 85.

¹²⁸ The claim was as follows:

“Use of taxol and sufficient medications to prevent severe anaphylactic reactions for manufacturing a medicamentation for simultaneous, separate or sequential application for the administration of from 135mg/m² up to 175 taxol over a period of about three hours or less as a means for treating cancer and simultaneously reducing neutropenia.”

¹²⁹ *BMS*, above n 78, para 63 (Aldous J).

¹³⁰ *Ibid.*, para 40.

the claim objectionable as directed to a method of medical treatment, but it also failed to satisfy the novelty requirement.

Following *BMS*, the UK Intellectual Property Office treated second medical use claims which defined the new use in terms of the method, time, frequency or dosage of administration as being unpatentable methods of treatment disguised as Swiss-type claims. Such claims were also considered to lack novelty.¹³¹ This approach was upheld by the Patents Court and Court of Appeal in *Merck and Co Inc's Patents*.¹³²

In 2008, the Court of Appeal departed from their decision in *BMS*. The claim to be considered in *Actavis v Merck*¹³³ included a new dosage regime of a compound to treat androgenic alopecia. Merck held a prior patent for the compound for use in the treatment of androgenic alopecia where the specified dosage was 5 mg daily. The issue in this case was the validity of a claim where the only novel feature resided in the new dosage amount of 0.05 to 1.0 mg per day. At first instance, the Patents Court held that the claim both lacked novelty and was a method of treatment excluded under section 4(2) of the Patents Act 1977. Both grounds of invalidity were based on the *BMS* decision.

The Court of Appeal reviewed the law of the EPO, Germany and New Zealand and recognised that in each of these jurisdictions, claims where novelty resides in a new dosage regime are treated as novel and not claims as to methods of medical treatment. Thus they held that “the position is settled.”¹³⁴ However it was necessary to consider whether they were bound by *BMS* to reach a different conclusion.

¹³¹ Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office, above n 82, para 120.

¹³² *Merck & Co Inc's Patent* (Pat. Ct.), above n 1; *Merck & Co Inc's Patents* [2004] FSR 330 (CA).

¹³³ [2007] EWHC 1311; [2008] EWCA Civ 444.

¹³⁴ *Actavis v Merck*, above n 85, para 44.

Concerning the novelty requirement, the Court of Appeal formed the opinion that there was no clear ratio decidendi in *BMS* that novelty could only reside in a second medical use claim if it is directed to the treatment of a new medical condition.¹³⁵ Based on the lack of such a precedent, the Court accepted that second medical use claims solely distinguished by a new dosage regime will be novel. It was recognised that there was a clear (albeit very narrow) ratio decidendi from *BMS* that “the claim concerned was essentially to a method of medical treatment.”¹³⁶ The Court in *Actavis v Merck* distinguished the claim before them on the grounds that there was nowhere near the level of involvement of medical personnel. Instead, the claim in *Actavis v Merck* was directed to use of the compound for the preparation of a medicament.¹³⁷ However, even if the claim had not been distinguishable from *BMS*, the Court said it would have departed from its own, earlier decision. For that reason also, the Patent Court’s conclusion about novelty and method of treatment was reversed.¹³⁸

(ii) New patient group

Swiss-type claims where novelty resides in the new patient group are acceptable in the UK. The UK Patent Office disagrees with the EPO decision of *Schering*,¹³⁹ insofar as the Board in that case asserted that a new patient group can overlap with patients treated in the prior art. Thus in order for a patent claim regarding a new patient group to be valid in the UK, the new patient group cannot overlap with the group previously treated.¹⁴⁰

Notwithstanding this, the Guidelines state that disclosure that a composition may be useful in treating a wider class of disease does not necessarily anticipate use in the

¹³⁵ *Ibid.*, para 71.

¹³⁶ *Ibid.*, para 73.

¹³⁷ *Ibid.*, para 75.

¹³⁸ *Ibid.*, para 107.

¹³⁹ *Schering*, above n 108, discussed above at para 2.3(a)(ii)(4).

¹⁴⁰ Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office, above n 82, para 131.

treatment of a specific form of that disease.¹⁴¹ Examples given include the use of an agent for treating pancreatic cancer as opposed to a number of other cancers,¹⁴² adenocarcinoma of the ovary compared with ovary cancer in general,¹⁴³ and hormone refractory prostate cancer rather than prostate cancer in general.¹⁴⁴

(iii) New technical effect of mechanism of action

Contrary to the position taken by the EPO, claims relating to a new technical effect or mechanism of action are rejected in the UK for lack of novelty.¹⁴⁵ However, if the discovery of a new technical effect determines a new patient group and that patient group is clearly defined, such a claim may be novel.¹⁴⁶

(c) *New Zealand*

(i) New method, time, frequency or dosage of administration

The earliest decision to consider the extension of Swiss-type claims in New Zealand was *Abbott Laboratories' Application*,¹⁴⁷ which approved of the UK case *BMS*.¹⁴⁸ *Abbott Laboratories' Application* concerned the acceptability of certain Swiss-type claims directed to the known use of a known compound, where novelty resided in the suitability for sequential or co-administration with a novel compound. Assistant Commissioner Popplewell held that the claims in question were analogous to those in *BMS* as they claimed the use of a known compound in the manufacture of a medicament with a known

¹⁴¹ *Ibid.*, para 116.

¹⁴² T 0385/07 *PHARMA MAR/Aplidine* (Unpublished) 5 October 2007.

¹⁴³ T 1001/01 *SMITHKLINE BEECHAM/Treatment of ovarian cancer* (Unpublished) 11 October 2007.

¹⁴⁴ *Praecis*, above n 101.

¹⁴⁵ Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office, above n 82, para 133.

¹⁴⁶ *Ibid.*, para 138.

¹⁴⁷ *Abbott Laboratories' Application*, P 16/2003, 11 August 2003.

¹⁴⁸ *BMS*, above n 78.

pharmaceutical activity. As such, the claims were unpatentable.¹⁴⁹

Several years after *Abbott Laboratories' Application*, Assistant Commissioner Hazlewood reached a different conclusion concerning patentability of new dosage regimes.¹⁵⁰ This case involved an application by Merck & Co which was opposed by Arrow Pharmaceuticals. The application concerned an improved dosage regime whereby a known compound was administered at a high relative dosage but at a low relative frequency. The Assistant Commissioner in this case chose not to apply the ratio from *BMS* and approved the contrary EPO decision in *Genentech*.¹⁵¹ Swiss-type claims directed to new dosage regimes were deemed patentable, Assistant Commissioner Hazlewood affirming that “there can be inventiveness in improving existing therapies and this is patentable by way of Swiss-type claim”. But despite satisfying the requirements of novelty and patentable subject-matter, the application failed on the ground of obviousness. On appeal to the High Court, however, Harrison J overturned the Assistant Commissioner’s decision regarding obviousness and the patent was granted.¹⁵²

Confusion in this area was settled by the decision in *Genentech's Application*.¹⁵³ The application considered in this case corresponds to that considered in the EPO *Genentech* case, namely the intermittent administration of IGF-1 for use in the treatment of chronic renal failure.¹⁵⁴ Assistant Commissioner Popplewell was once again faced with the question of whether claims were permissible where novelty resided purely in a new dosage regime. The Assistant Commissioner reconsidered his prior decision in *Abbott Laboratories' Application* where he had held such claims to be invalid. It was reasoned that the decision in that case concerned a claim where novelty resided in co-

¹⁴⁹ *Abbott Laboratories Application*, above n 147, p 17.

¹⁵⁰ *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*, P3/2006, 31 January 2006.

¹⁵¹ *Genentech*, above n 99; discussed above at para 2.3(a)(i)(1).

¹⁵² *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd* [2007] 70 IPR 667 (HC).

¹⁵³ *Genentech's Application*, P1/2007, 23 January 2007.

¹⁵⁴ *Genentech*, above n 99; discussed above at para 2.3(a)(i)(1).

administration, and as such was not intended to be authority for a general principle. Subsequent international developments were discussed, in particular the fact that the decision in *Abbott Laboratories' Application* was made without the benefit of the reasoning in the European *Bristol-Myers* case,¹⁵⁵ *Genentech*¹⁵⁶ or the comments of Jacob J in *Merck & Co Inc's Patents*.¹⁵⁷ The only contrary view was that of the UK Court of Appeal in *BMS*,¹⁵⁸ which was not binding. Consequently, the Assistant Commissioner departed from the approach stipulated in the IPONZ Guidelines and concluded he should apply the principles set out in *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*.¹⁵⁹

(ii) New patient groups

*AstraZeneca AB's Application*¹⁶⁰ concerned the validity of a claim where novelty resided in a new patient group. The claim was directed to the use of fulvestrant in the treatment of breast cancer in patients who had previously been treated unsuccessfully with an aromatase inhibitor and tamoxifen. IPONZ objected to the granting of a patent, as fulvestrant was already known to treat breast cancer.

Assistant Commissioner Hazlewood held that if it is discovered that a known treatment is effective in treating a new group of patients, where it was previously unknown that they would derive any effect from such treatment, this is a patentable improvement. In reaching this conclusion, decisions of the EPO were considered. It was recognised that New Zealand adopted Swiss-type claims from European authorities, and the Court of Appeal had acknowledged that New Zealand practice was little different from the EPC. Therefore the Assistant Commissioner concluded that we ought to follow EU decisions

¹⁵⁵ *Bristol-Myers Squibb Company Application* (EPO Opposition Division), 22 May 2002.

¹⁵⁶ *Genentech*, above n 99.

¹⁵⁷ *Merck & Co Inc's Patent*, above n 1.

¹⁵⁸ *BMS*, above n 78.

¹⁵⁹ *Merck v Arrow*, above n 150.

¹⁶⁰ *AstraZeneca AB's Application*, above n 123.

regarding claims directed to new patient groups.¹⁶¹

The EPO decision in *Schering* was considered.¹⁶² Assistant Commissioner Hazlewood's interpretation of this case is questionable. The Assistant Commissioner construed the decision in *Schering* as departing from the second *Medco Research* requirement (concerning the arbitrary selection of the new patient group).¹⁶³ There was no mention of the principle that the new group cannot overlap with the prior patient group. However the Assistant Commissioner appears to have misinterpreted *Schering*. The TBA in fact rejected outright the first requirement from *Medco Research* (that there be no overlap between the prior and new patient groups). The TBA also appeared to reject the second requirement, but since it emphasised that this condition was in fact fulfilled in *Schering* it remains uncertain whether the second requirement has indeed been removed. The Assistant Commissioner's arguably erroneous interpretation of *Schering* was not critical as he was not required to decide whether to reject or accept the decision in *Schering*.¹⁶⁴

(iii) IPONZ Guidelines for the examination of Swiss-type claims

Updated guidelines for the examination of Swiss-type claims were released by IPONZ in April 2009.¹⁶⁵ These Guidelines are expansive and expressly permit certain extended Swiss-type claims. It is important to note, however, that these Guidelines are simply to guide IPONZ examiners; they do not constitute legal authority.

¹⁶¹ *Ibid.*, p 16.

¹⁶² *Schering*, above n 108, discussed above at para 2.3(a)(ii)(4).

¹⁶³ *AstraZeneca AB's Application*, above n 123, p 15.

¹⁶⁴ *Ibid.*, p 17.

“Even accepting that the second criterion of *Medco*, which appears to be superceded [sic.] by *Schering*, is applicable, the new patient group is not arbitrary. Where a cancer is multiple resistant, resulting from physiological and/or pathological factors, there must be a functional relationship between the efficacy of the treatment and the cancer.”

¹⁶⁵ IPONZ Practice Guidelines for the examination of Swiss-type claims (updated 8 April 2009), available at < <http://www.iponz.govt.nz/cms/patents/patent-topic-guidelines/2004-business-updates/guidelines-for-the-examination-of-swiss-type-claims?searchterm=swiss> > last accessed 6/10/09.

The Guidelines accept Swiss-type claims where the purported novelty of the new use resides in the new mode of administration or dosage regime. Where the purported new use relates to a new patient group, such claims will be accepted only if the criteria from *Medco Research* are satisfied. The new patient group must have a distinct physiological or pathological difference which is neither arbitrary nor overlapping with a known patient group. In order to determine whether there is merely an arbitrary difference, IPONZ will look at whether there is a functional relationship between the physiological or pathological status and the therapeutic effect achieved.¹⁶⁶ There is no reference to the decision in *Schering* in the Guidelines, which suggests that IPONZ has implicitly rejected this decision.

The Guidelines also consider claims where novelty resides in a new mechanism of action or technical effect. Unlike the EU which accepts such claims, these will be refused by IPONZ as such information is deemed to be merely a discovery.¹⁶⁷

2.4 Where to from here?

The advantages of Swiss-type claims are less convincing with respect to the extended form of claim. The further the scope of Swiss-type claims is extended, the more questionable this form of protection becomes. Although objections have been made based on the fact that these claims lack novelty and are directed to a method of medical treatment, assuming the orthodox form of claim is accepted, there is no reason why extended Swiss-type claims should be refused on these grounds. The real objection with these claims lies not in their form, but in their application. Certain applications involving extended Swiss-type claims should be refused for lack of inventive step.

¹⁶⁶ Ibid.

¹⁶⁷ Ibid.

The subject-matter of an extended Swiss-type claim may be a mere discovery, which does not fulfil the ‘inventive step’ requirement of patentability. As the law stands, there is no requirement to examine for inventive step under the Patents Act 1953. This is remedied in the Patents Bill 2008. Inclusion of the requirement to examine for inventive step will ensure patents are not granted for obvious improvements, but only if examination is adequate.

An example of inadequate examination is seen in the decision of Harrison J in *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*,¹⁶⁸ discussed above at paragraph 2.3(c)(i). Obviousness was one of the grounds of opposition on which the proceedings were initiated. Although Assistant Commissioner Hazlewood refused the patent based on lack of inventive step, this decision was overturned by Harrison J and the patent granted. The same application was considered in Australia, where the new dosage regime could be directly claimed. In the Federal Court, Gyles J concluded that the method claims in question were merely directions for use and did not constitute a manner of manufacture that qualified as an invention.¹⁶⁹ The Full Court of the Federal Court upheld the decision of Gyles J and stated that there was no invention disclosed in the specification.¹⁷⁰ Both courts also ruled the claims were not novel.¹⁷¹ A corresponding application was rejected in the UK, based on the principle in *BMS*.¹⁷² The EPO found that the application concerned an invention, but the patent was revoked for lack of novelty and inventive step.¹⁷³ Therefore New Zealand is the only jurisdiction where the claim was found to relate to patentable subject-matter that was novel and inventive. The requirement of examination for inventive step in the Patents Bill 2008 may therefore be insufficient if New Zealand

¹⁶⁸ *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*, above n 152.

¹⁶⁹ *Arrow Pharmaceuticals Ltd v Merck & Co Inc* (2004) 63 IPR 85 (FC), para 87.

¹⁷⁰ *Merck & Co Inc v Arrow Pharmaceuticals Ltd* (2006) 68 IPR 511 (FCAFC), para 75.

¹⁷¹ *Arrow Pharmaceuticals Ltd v Merck & Co Inc*, above n 169, para 116; *Merck & Co Inc v Arrow Pharmaceuticals Ltd*, above n 170, para 102.

¹⁷² *Merck & Co Inc's Patent* (CA), above n 132.

¹⁷³ *Merck & Co Inc*, Opposition Division, 19 August 2004; cited in *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*, above n 150, p 42.

judges apply the requirement in a more relaxed manner than courts elsewhere.

Failing dramatic remodelling of the law in New Zealand, orthodox Swiss-type claims are here to stay. Although not addressed in the Patents Bill 2008, orthodox Swiss-type claims have been accepted by the Court of Appeal and IPONZ. On passage of the Bill it will be fair to conclude that Parliament has, by implication, accepted the use of orthodox Swiss-type claims. The same cannot be said for extended Swiss-type claims, where the first acceptance by IPONZ of any form of extension occurred in 2006.¹⁷⁴ Nonetheless, extended Swiss-type claims should continue to be accepted in New Zealand so long as they are novel and involve an inventive step. As the UK Court of Appeal pointed out in *Actavis v Merck*, most dosage regimes will be obvious; only in an “unusual case” would specifying a dosage regime confer validity on an otherwise invalid claim.¹⁷⁵ However where such claims are both inventive and novel, patent protection should be conferred.

The direct form of claim permitted in the EU and the UK should not be accepted or incorporated into New Zealand legislation. Such claims are in blatant breach of the methods of medical treatment prohibition and there is nothing to preclude patentees from enforcing these claims against practitioners.

¹⁷⁴ The Patents Bill 2008 was introduced into Parliament on 9 July 2008, although review of the Patents Act 1953 began in 1990.

¹⁷⁵ *Actavis v Merck*, above n 85, para 32.

III. A FUTURE APPLICATION? SWISS-TYPE CLAIMS AND PHARMACOGENOMICS

3.1 An overview of pharmacogenomics

Pharmacogenomics is an emergent field which is rapidly gaining support throughout the scientific community. It can be described as a form of ‘personalised medicine’ and concerns the influence of the human genome on the body’s response to drugs.¹⁷⁶ In brief, pharmacogenomics examines the effect genetic variations have on drug efficacy and toxicity.

This chapter considers the potential applicability of Swiss-type claims to pharmacogenomic inventions. There is no attempt to analyse the likelihood of these inventions entering the market, nor is the economic viability of such inventions considered in detail. Policy-makers need to contemplate how this area is best regulated to foster research and development, whilst weighing up a number of ethical, social, political and economic issues. However given the unsettled nature of pharmacogenomics, such analysis may not occur for some time. Consequently, the purpose of this chapter is to emphasise that pharmacogenomic inventions ought to attract patent protection, and to propose that such protection might take the form of Swiss-type claims. Although there is a vast amount of literature pertaining to the individual fields of pharmacogenomics and Swiss-type claims, little has been written about the interface between these areas.

A detailed analysis of the science behind pharmacogenomic inventions is beyond the scope of this paper. Nonetheless, understanding the concepts of pharmacogenomics is

¹⁷⁶ This is the definition provided by the International Society of Pharmacogenomics; cited in Q Shi, “Patent system meets new sciences: is the law responsive to changing technologies and industries?” (2005) 61 NYU Annual Survey of American Law 317, 341.

vital to understanding how Swiss-type claims may be applicable to these inventions so an elementary level explanation of the scientific aspects of pharmacogenomics will be provided.

3.2 One size does *not* fit all

As discussed in paragraph 1.2, it can cost up to almost US\$1 billion to bring a new pharmaceutical to the market.¹⁷⁷ A sizeable proportion of this sum underwrites clinical trials that drug manufacturers are required to carry out in order to ensure the safety and efficacy of the drug. However, it has been estimated that only 50% of all pharmaceuticals prescribed actually produce the desired therapeutic effects.¹⁷⁸ Not only is there the possibility that the drug will have no effect in the patient; there also exists a more serious risk that it will cause an adverse drug reaction (ADR). A study calculated the overall incidence of ‘serious’¹⁷⁹ ADRs to be 6.7% of hospitalised patients, equating to over 2.2 million hospitalised patients in the United States in 1994 alone. Such ADRs caused over 100,000 deaths, making these reactions between the fourth and sixth leading cause of death that year.¹⁸⁰

The failure of drugs to achieve desired therapeutic results, and their role in producing ADRs, has invariably been linked with patients’ genetic profiles. Although an individual’s

¹⁷⁷ DiMasi *et al.*, above n 20, p 180.

¹⁷⁸ B Spear, M Heath-Chiozzi and J Huff, “Clinical application of pharmacogenomics” (2001) 7 Trends in Molecular Medicine 201; cited in G Hill, “Pharmacogenetics: A Review of the Ethical, Social and Policy Implications of ‘Personalised Medicine’” in Human Genome Project, *Genes, Society and the Future (volume III)* (Brookers, 2009) 393, 397. This study found that the average efficacy of drugs in 14 therapeutic areas was 51.5%.

¹⁷⁹ Defined as requiring hospital admission.

¹⁸⁰ J Lazarou, B Pomeranz and P Corey, “Incidence of adverse drug reactions in hospitalised patients: a metaanalysis of prospective studies” (1998) 279 Journal of the American Medical Association 1200.

genome is by no means the sole cause of how a drug acts (or indeed why it may not act), it is now widely accepted that it is a major contributing factor.¹⁸¹

(a) The promises and possibilities of pharmacogenomics

Pharmacogenomics explores the contribution of genetics to drug efficacy and safety, specifically considering how genetic variations affect individuals' responses to drugs.¹⁸² The idea behind pharmacogenomics is straightforward. Rather than producing broad-spectrum drugs for use in all patients, pharmacogenomics promises to personalise medicine by providing targeted pharmaceuticals to fit the genetic profile of each individual.¹⁸³ Its strategy is to separate patients into specific diagnostic categories that correlate more strongly with certain therapies or preventative measures.¹⁸⁴ For example, although a drug may be only 50% effective in patients with a certain disease, it may be 85% effective in a subgroup comprised of 60% of total patients. Similarly, a drug that is toxic in 25% of patients may only be toxic in 2% of an appropriately identified subgroup.¹⁸⁵ Reducing ADRs and increasing efficacy of drugs are the two central objectives of pharmacogenomics.

¹⁸¹ U Meyer, "Pharmacogenetics and adverse drug reactions" (2000) 356 *The Lancet* 1667.

¹⁸² L Tucker, "Pharmacogenomics: A Primer for Policymakers" (2008) National Health Policy Forum Background Paper 3, available at <http://www.nhpf.org/library/background-papers/BP_Pharmacogenomics_01-28-08.pdf> last accessed 6/10/09.

¹⁸³ K Paterson-Iyer, "Pharmacogenomics, ethics, and public policy" (2008) 18 *Kennedy Institute of Ethics Journal* 35.

¹⁸⁴ Report of the President's Council of Advisors on Science and Technology, "Priorities for Personalised Medicine" (September 2008) p 23, available at <http://www.ostp.gov/galleries/PCAST/pcast_report_v2.pdf> last accessed 6/10/09.

¹⁸⁵ A Nunnally, S Brown, G Cohen, "Intellectual Property and Commercial Aspects of Pharmacogenomics" in M Rothstein (ed) *Pharmacogenomics: Social, Ethical and Clinical Dimensions* (Wiley & Sons, 2003) 109, 129.

(b) Pharmacogenomics vs pharmacogenetics

The idea of genetic variation influencing drug efficacy is not a new concept. The theory was first proposed by Motulsky in 1957,¹⁸⁶ who coined the term 'pharmacogenetics'. Fifty years later, the underlying concepts have been expanded following completion of the Human Genome Project and the development of techniques such as functional genomics and high throughput screening.¹⁸⁷ Whilst pharmacogenetics simply considers inherited differences in drug absorption, metabolism and elimination, the more extensive field of pharmacogenomics considers all the genes that determine drug behaviour.¹⁸⁸ Nonetheless, the terms pharmacogenomics and pharmacogenetics are often used interchangeably. This paper focuses on pharmacogenomics and that term will be used throughout.

(c) An elementary overview of the science behind pharmacogenomics

Genes determine the makeup of enzymes, receptors, transporters and other proteins involved in drug and disease pathways.¹⁸⁹ Polymorphisms or mutations in the coding regions of these genes can thus alter the efficacy and toxicity of drugs.¹⁹⁰ Such polymorphisms act as biomarkers in pharmacogenomics. The most prevalent form of genetic variation is a single nucleotide polymorphism (SNP), which is the substitution of a

¹⁸⁶ A G Motulsky, "Drug Reactions, Enzymes and Biochemical Genetics" (1957) 165 *Journal of the American Medical Association* 835; cited in B Williams-Jones and V Ozdemir, "Enclosing the 'Knowledge Commons': Patenting Genes for Disease Risk and Drug Response at the University-Industry Interface" in C Lenk, N Hoppe and R Andorno (eds), *Ethics and Law of Intellectual Property* (Ashgate Publishing Limited, 2007) 137, 150.

¹⁸⁷ L T Vaszar, G D Rosen and T A Raffin, "Pharmacogenomics and the challenge to privacy" (2002) 2 *The Pharmacogenomics Journal* 144.

¹⁸⁸ N Khaleeli and D Fernandez, "Patent Prosecution in Pharmacogenomics" (2006) 88 *Journal of the Patent and Trademark Office Society* 83, 85.

¹⁸⁹ Tucker, above n 182, p 3.

¹⁹⁰ Meyer, above n 181, p 1668.

single base pair for another.¹⁹¹ While the majority of these have no effect at all, SNPs may give rise to disease, increased susceptibility to disease, sensitivity or insensitivity to certain drug treatments, or adverse side effects from those treatments.¹⁹² The study of these variations is therefore indispensable in understanding disease and effective personalised treatment.

(d) Benefits of pharmacogenomics for society

The benefits of pharmacogenomics are numerous. Not only will pharmacogenomics improve healthcare by better targeting medicines to patients who will respond favourably, but this field is also important from an economic perspective.

The cost of healthcare is on the rise. The escalating cost of healthcare due to the 'baby boomers' generation approaching retirement age is causing problems for governments worldwide, and strategies are being employed to keep these costs down. While most strategies involve making choices concerning access to or quality of care, pharmacogenomics promises to reduce costs without compromising patient care for a number of reasons.¹⁹³ Firstly, reducing the number of ADRs will result in fewer hospital visits and shorter subsequent rehabilitative care. A recent study has attempted to determine savings that would result from integrating genetic testing into routine warfarin therapy in the United States. The results suggest that such testing would avoid 85,000 serious bleeding events and 17,000 strokes annually, and save \$1.1 billion in healthcare spending each year.¹⁹⁴ Secondly, ability to distinguish in advance those patients who will

¹⁹¹ It has been estimated that approximately 15 million common SNPs exist in human populations (E Pennisi, "Breakthrough of the year: Human Genetic Variation" (2007) 318 Science 1842).

¹⁹² Nunnally, above n 185, p 114.

¹⁹³ Report of the President's Council of Advisors on Science and Technology, above n 184, p 19.

¹⁹⁴ A McWilliam, R Lutter and C Nardinelli, "Healthcare savings from personalizing medicine using genetic testing: the case of warfarin" (November 2006) AEI-Brookings Joint Center for Regulatory Studies, Working Paper 06-23, available at <<http://aei-brookings.org/publications/abstract.php?pid=1127>> last accessed 6/10/09; cited in Tucker, above n 182, p 3.

benefit, from those who will not, will result in more accurate prescribing.¹⁹⁵ The consequence will be fewer visits to practitioners, a decrease in the length of time patients are on medication, and a decrease in the number of medications required before finding an effective therapy.

Proponents of pharmacogenomics also anticipate that savings from drug development will be reflected in the cost of drugs. It has been estimated that pharmacogenomics could result in savings of up to \$335 million for the development of one drug, compared with development costs of non-targeted medicaments.¹⁹⁶ However this is an economically complex matter; although drug development will be cheaper, the target market will be smaller therefore higher drug prices may be required to recover investments.

(e) Examples of targeted medications in the market

Although the widespread application of pharmacogenomics in treating disease is not yet commonplace, a number of pharmaceuticals and diagnostic tests have entered the market based on pharmacogenomic studies. Two commonly cited examples of drugs linked with genetic variation are 6-mercaptopurine (6-MP) and trastuzumab.

The anti-leukaemic drug 6-MP is normally metabolised by the enzymatic action of thiopurine methyltransferase (TPMT), which converts 6-MP into inactive compounds. However a small percentage of individuals have a mutation in the gene that codes for the TPMT enzyme, which leads to decreased TPMT activity. If a patient treated with 6-MP has such a mutation, a life-threatening condition called myelosuppression may result from accumulation of 6-MP. Currently, testing for mutations in the TPMT gene before

¹⁹⁵ Report of the President's Council of Advisors on Science and Technology, above n 184, p 13.

¹⁹⁶ The Boston Consulting Group, "A Revolution in R&D: How Genomics and Genetics are Transforming the Biopharmaceutical Industry" (November 2001), available at <www.bcg.com/impact_expertise/publications/files/eng_genomicsgenetics_rep_11_01.pdf> last accessed 6/10/09.

administering 6-MP is the most frequently performed pharmacogenomic test in New Zealand and Australia.¹⁹⁷

It is not only inherited DNA which is of significance in predicting drug response; the genetic profile of a cancerous tumour, for example, may also affect drug efficacy. This is the case with the 25-30% of breast cancer patients who over-express the HER2 gene.¹⁹⁸ This over-expression results in amplification of HER2 receptors which leads to enhanced cell proliferation and ultimately formation of a tumour. Patients with this genetic profile may have differential responses to a variety of agents. One such medication to which patient response varies depending on HER2 expression is trastuzumab (Herceptin™). Trastuzumab binds to HER2 receptors and inhibits proliferation and survival of HER2-dependent tumours.¹⁹⁹ Use of trastuzumab is therefore based on patient selection by genotyping. The drug is administered to patients with HER2 overexpressing breast cancer in association with the HercepTest™.²⁰⁰

6-MP and trastuzumab are just two examples of drugs currently administered in concert with genetic tests. The efficacy and toxicity of a number of other drugs can be predicted by genetic tests, and this number is increasing exponentially as the field burgeons.

3.3 A pharmacoeconomic perspective

The introduction of pharmacogenomic technologies promises not only to profit consumers; there are a number of economic benefits from a production point of view.

¹⁹⁷ Hill, above n 178, p 409.

¹⁹⁸ D J Slamon, G M Clark, S G Wong, W J Levin, A Ullrich and W L McGuire, "Human breast cancer: correlation of relapse and survival with amplification of the HER-2/*neu* oncogene" (1987) 235 *Science* 177.

¹⁹⁹ C A Hudis, "Trastuzumab – the mechanism of action and use in clinical practice" (2007) 357 *New England Journal of Medicine* 39.

²⁰⁰ Hill, above n 178, p 414.

Economic models indicate that incentives to engage in pharmacogenomic research and development will vary according to the patent status of the drug involved and various market conditions.²⁰¹ Four classes of drug will be considered below; ‘new’ drugs, ‘on-patent’ drugs, ‘off-patent’ drugs and ‘failed’ drugs. Whether availability of extended Swiss-type claims would provide a necessary incentive is analysed.

Pharmacogenomics promises to dramatically reduce the cost of new drug development. Tailoring pharmaceuticals to the specific genetic makeup of individuals is estimated to reduce the cost of clinical trials by 30-40%.²⁰² Although these drugs will be marketed for use in a defined genetic subpopulation, greater efficacy will support premium drug prices. Furthermore, genomic technologies can be used to identify new indications for existing drugs, extending their market life and profitability. However, current patent protection for pharmacogenomic inventions concerning new drugs, and new medical indications, for existing drugs is likely to be adequate. A new pharmaceutical will be protected by way of a product claim, as the compound itself is novel. New indications of existing drugs will be patentable by way of orthodox Swiss-type claims, whereby use of the composition in the manufacture of a medicament for treatment of a new disease is claimed.

Pharmacogenomic research concerning drugs which are ‘on-patent’ may be carried out in order to minimise ADRs or increase the efficacy of these drugs. However for drugs currently marketed to the general population, pharmacogenomic research represents a major change in strategy. Restricting the use of drugs based on genotype fragments the market of on-patent drugs and may reduce revenues due to prevention of the “sizeable lawful trade”²⁰³ in ineffective drugs. Drug companies therefore have little incentive to develop genetic tests or produce information that notifies a significant proportion of

²⁰¹ M J Meurer, “Pharmacogenomics, Genetic Tests, and Patent-Based Incentives” in F S Kieff (ed), *Perspectives on Properties of the Human Genome Project* (Academic Press, 2003) 299; cited in A Nunnally, “Intellectual Property Perspectives in Pharmacogenomics” (2006) 46 *Jurimetrics* 249, 261.

²⁰² The Boston Consulting Group, above n 196, p 12.

²⁰³ Evans, above n 53, p 1289.

consumers that their medication is of little effect. This lack of incentive for such research may be remedied by Swiss-type claims, which could extend the term of patent protection available, albeit for a smaller target market.

Generic versions of ‘off-patent’ drugs will be available, as innovator pharmaceutical companies will have no monopolies over compounds once patents expire. Consequently, the promise of a further term of protection will provide an incentive for the industry to determine new patient groups within which the drug is particularly effective. The use of Swiss-type claims in protecting pharmacogenomic knowledge regarding off-patent drugs will be important in encouraging drug companies to improve efficacy or decrease side effect profiles in particular patient subpopulations.

Finally, pharmacogenomic targeting could allow for the ‘rescue’ of drugs which have been abandoned in the early stages of drug development, that failed to attain regulatory approval, or that were removed from the market for safety reasons.²⁰⁴ Administration in a subset of patients with a certain genetic profile may prove to be both effective and safe. If the patent term for such a drug has expired, or is close to expiry, without promise of a further patent term, there will be no incentive to investigate the possibility of restoring this drug to the market for use in a defined group. The potential application of Swiss-type claims in this area may encourage the resurrection of these ‘failed’ drugs.

Pharmacogenomics is a developing field and precise economic analyses have not yet been carried out. To date, it is uncertain whether pharmacogenomics will bring sufficient financial benefits to justify investment.²⁰⁵ However it is clear that research in all classes will only occur if there is adequate patent protection to provide drug companies with incentives to engage in such studies.

²⁰⁴ Hill, above n 178, p 398.

²⁰⁵ A Walthall, “Legal Pressure to Incorporate Pharmacogenetics in the UK” (2006) 46 *Jurimetrics* 263, 264.

3.4 Limitations of patent protection afforded to pharmacogenomics

As the principal asset derived from pharmacogenomic research is *information* concerning relationships between genomic variation and drug response, questions arise as to the best means of protecting that information by patent.²⁰⁶ Currently, such information attracts protection by way of patents for genetic sequences and for genetic tests.

(a) Genetic sequence patents

Genetic sequences are patentable in most jurisdictions, including New Zealand. In fact, more than 25,000 DNA-based patents were granted worldwide by 2000.²⁰⁷ In New Zealand, a gene patent covers the gene when isolated and purified; it does not confer protection to the gene when found in nature.²⁰⁸

It is possible that genetic sequence patents may be granted in the field of pharmacogenomics. Such patents will be uncommon as often discoveries in this field simply identify a correlation between a known sequence (or certain polymorphism) and a drug response. Nonetheless this remains a possibility.

Controversy surrounding the patenting of genes threatens the value of gene patents. Law reform may lead to stricter patentability requirements, or possibly refusal of gene patents altogether. Gene patents are controversial for a number of reasons. Ethical objections are based on a disapproval of the association of property rights with what is considered the basic core of humanity. Legal objections are raised as genes may be viewed as discoveries

²⁰⁶ Shi, above n 176, p 342.

²⁰⁷ R M Cook-Deegan and S J McCormack, "Intellectual Property: Patents, Secrecy and DNA" (2001) 293 Science 217.

²⁰⁸ Ministry of Economic Development *Implications of the Granting of Patents over Genetic Material, A Cabinet Paper* (Wellington, 2003), para 10, available at <<http://www.med.govt.nz/upload/2927/implications.pdf>> last accessed 6/10/09.

not inventions, therefore failing to meet the legal criteria for patentability. A further assertion is that genes are merely products of nature and therefore not 'new'.²⁰⁹

Yet the most significant criticism of gene patents concerns their scope. A patent application in New Zealand need not identify any specific use for the gene, yet rights will be granted that cover all uses to which the genetic material might be put.²¹⁰ This is particularly problematic as any further research into gene functions or diagnostic testing necessarily requires the use of the patented DNA.²¹¹ As seen in the BRCA/Myriad saga,²¹² upstream patents can become tollbooths that increase costs and slow downstream research.²¹³

Adoption of the Patents Bill 2008 would restrict the scope and availability of gene patents. As discussed in paragraph 1.1, the examination procedure under the Patents Act 1953 is comparatively lenient. However the Explanatory Note to the Patents Bill 2008 specifically refers to the introduction of examination for inventiveness and usefulness in order to limit the scope of gene patents.

Aside from proposed changes in the Patents Bill 2008, gene patents may be further restricted. The amendments proposed in the Bill are already present in the patent laws of

²⁰⁹ Organisation for Economic Co-Operation and Development "Genetic Inventions, Intellectual Property Rights and Licensing Practices" (2002) p 11, available at <<http://www.oecd.org/dataoecd/42/21/2491084.pdf>> last accessed 6/10/09. For a review of the controversy surrounding gene patents, see J Gibson "The Discovery of Invention: Gene Patents and the Question of Patentability" (2007) 12 *Journal of Intellectual Property Rights* 45.

²¹⁰ Ministry of Economic Development, above n 208, para 15.

²¹¹ Ministry of Economic Development, above n 208, para 11.

²¹² The BRCA/Myriad saga refers to the furore that erupted over the patenting of the BRCA1 and BRCA2 genes, which affect the risk of hereditary breast and ovarian cancer. Myriad Genetics Inc acquired a number of patents internationally over these genes, genetic variations and tests to identify such variations, which they subsequently attempted to enforce. These patents not only hindered research involving these genes, but also restricted accessibility of diagnostic testing for breast and ovarian cancer. The BRCA/Myriad history is discussed fully by: M Rimmer, *Intellectual Property and Biotechnology* (Edward Elgar, 2008) 187; E Marshall, "Lawsuit challenges legal basis for patenting human genes" (2009) 324 *Science* 1000; and N Siva, "Myriad wins BRCA1 row" (2009) 27 *Nature* 8.

²¹³ Williams-Jones and Ozdemir, above n 186, 146.

many countries,²¹⁴ nonetheless there remains a significant amount of international debate regarding the scope of patents pertaining to genes and genetic applications. The Australian Law Reform Commission has produced a report with recommendations for reform²¹⁵ and the Australian Parliamentary Senate Committee is currently looking into whether gene patents should be allowed.²¹⁶ A working party on behalf of the European Society of Human Genetics has recommended updating European rules to limit patents on genes and DNA sequences.²¹⁷ In the United States, the Secretary's Advisory Committee on Genetics Health and Society is preparing a policy report examining the effects of patenting and licensing on access to genetic testing.²¹⁸ Several patent reform bills have been introduced,²¹⁹ and earlier this year the American Civil Liberties Union and Public Patent Foundation commenced proceedings challenging the patentability of genes in the United States. Furthermore, following the decision in *Ex parte Kubin*²²⁰ last year, commentators have predicted that the scope of current genetic sequence patents and future attainment of such patents will be severely restricted. Therefore it is likely that the changes proposed in the Patents Bill 2008 will be followed with further more radical amendments in due course. Given the unsettled state of the law regarding the patentability of genes, it is wise to consider alternative options for patenting pharmacogenomic knowledge.

²¹⁴ Ministry of Economic Development, above n 208, para 27.

²¹⁵ Australian Law Reform Commission *Genes and Ingenuity: Gene Patenting and Human Health Report 99* (Canberra, 2004), available at <<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>> last accessed 10/10/09.

²¹⁶ Australian Parliamentary Senate Committee on Community Affairs, Inquiry into Gene Patents (ongoing), available at <http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents/> last accessed 8/10/09.

²¹⁷ S Soini, S Aymé, G Matthijs and members of the European Society of Human Genetics Working Party of Patenting and Licensing, "Patenting and licensing in genetic testing: ethical, legal and social issues" (2008) 16 *European Journal of Human Genetics* S10.

²¹⁸ Secretary's Advisory Committee on Genetics Health and Society, *Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (Bethesda, 2009), available at <<http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Consultation%20Draft%203%209%202009.pdf>> last accessed 10/10/09.

²¹⁹ The Genomic Research and Diagnostic Accessibility Act of 2002 and the Genomic Research and Accessibility Act of 2007 have both been proposed.

²²⁰ The decision in *Ex parte Kubin* 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007) is discussed in M Yamanaka, "A nail in the coffin for DNA sequence patents?" (2008) 26 *Nature Biotechnology* 1085.

(b) Genetic test patents

Currently, information derived from pharmacogenomic research is routinely utilised in the development of genetic tests. Such tests administered in concert with a drug are known as 'linked pharmacogenomics-based diagnostics' or 'companion diagnostics'. Companion diagnostics identify genetic polymorphisms that correlate with drug response, in order to determine the most appropriate drug therapies for individual genotypes.²²¹ Genetic tests are patentable and researchers recoup development costs by charging relatively high prices for administration of these tests.

The reliance on genetic test patents as incentives for pharmacogenomic research presents two potential limitations.

(i) The use of genetic tests is more limited

Genetic test patents are likely to generate considerably less revenue than that of drug patents. These tests are used only once per patient, compared with drug regimes where research and development costs can be recouped over the course of the therapy. This anomaly is apparent in the differing revenues of Herceptin™ and HercepTest™; in 2006, the revenue generated by sales of the Herceptin™ totalled \$1.2 billion, whereas that of HercepTest™ was in the tens of millions.²²² The limited revenues produced from genetic tests may not provide adequate incentives for pharmacogenomic research.

²²¹ J Altin, "Pharmacogenomics: A New Frontier for the Evergreening of Pharmaceutical Drugs" (2007) ANU College of Law Research Paper No. 08-04, available at <<http://ssrn.com/abstract=1129064>> last accessed 6/10/09.

²²² S Little, "IVDs for Personalized Medicine: Business opportunities and commercial challenges in personalized medicine" (2008) IVD Technology 35, available at <<http://www.devicelink.com/ivdt/archive/08/04/008.html>> last accessed 6/10/09.

(ii) Low-cost genome sequencing may undercut the value of genetic test patents

Genetic tests may soon be a thing of the past. Recent advances in genomic sequencing threaten to render genetic tests worthless, with obvious follow-on effects for the patents protecting such tests. It is anticipated that in the next 5 years, whole genome sequencing of individuals will be available for less than \$1000 per genome.

The Human Genome Project was embarked upon in 1990. The goal of the Human Genome Project was to provide researchers with powerful tools to understand the genetic factors involved in human disease, paving the way for new strategies for diagnosis, treatment and prevention.²²³ Once whole genotyping is within easy financial reach, it is likely to be used on mass for medical purposes.²²⁴

The first complete human genome sequenced cost nearly US\$3 billion and took 13 years to complete. The second was completed for US\$300 million. In 2007, the third genome was sequenced for US\$1 million.²²⁵ In fact, the use of genomic technology has moved outside the clinic and into the marketplace in recent years. It is now possible for individuals to purchase their own genome sequence from Knome Inc., a commercial company offering a personal genome sequencing service for the current price of US\$99,500. As part of this service, the individual receives reports that describe the genetic basis of specific conditions, and map known gene-to-disease associations onto the individual's personal DNA sequence.²²⁶

²²³ The Human Genome Project: Fact Sheet, available at <<http://www.nih.gov/about/researchresultsforthepublic/HumanGenomeProject.pdf>> last accessed 6/10/09.

²²⁴ J A Robertson, "The \$1000 Genome: Ethical and Legal Issues in Whole Genome Sequencing of Individuals" (2003) 3 *The American Journal of Bioethics* W35.

²²⁵ A Duncan, "Precognition – Predicting the Future: Biotechnology and Policing in 2020" (2008) 40 *Australian Journal of Forensic Sciences* 25.

²²⁶ Knome Inc, available at <<http://www.knome.com/home/>> last accessed 6/10/09.

As the price of whole genome sequencing continues to plummet, the value of genetic tests will likewise fall. Although not yet a reality, there is no lack of encouragement or incentives in the race to achieve the \$1000 genome. In addition to a number of financial rewards, the United States National Institute of Health has launched a \$70 million grant program to support researchers working to sequence a complete genome for \$1000.²²⁷ Sequencing technology advances, supported in part through this program, have led to the development of new sequencing chemistries and the commercial release of several next generation sequencing machines.²²⁸

A proviso on this hype must be noted. It is overly simplistic to assert that if people can purchase their genome sequence for \$1000, they will therefore be able to interpret it in accordance with the literature relating to pharmacogenomics.²²⁹ This is an issue to be considered by commercial companies offering such services. As noted above, companies such as Knome Inc. claim that individuals will be provided with reports that map known gene-to-disease associations.²³⁰ It is likely that in future, known gene-to-drug associations will also be able to be mapped. The question will then arise whether such mapping or interpretation of genome sequences would be an infringement of patents protecting genetic sequences and genetic tests.

Although the elusive \$1000 genome is not yet a reality, the decreasing cost of genome sequencing indicates that this is increasingly feasible. The consequence of an affordable form of genome sequencing would result in far fewer individuals electing to pay for specific genetic tests. The value of companion diagnostics may therefore be undermined by developments in genome sequencing in the coming years. Given the speed with which

²²⁷ Amongst these is the \$500,000 promised by the J. Craig Venter Science Foundation for the first team to bring the cost down to \$1000 per genome. The X Prize Foundation has also offered US\$10 million to the first team to sequence 100 genomes in 10 days at less than \$10,000 apiece (see R F Service, "The race for the \$1000 genome" (2006) 311 *Science* 1544).

²²⁸ Report of the President's Council of Advisors on Science and Technology, above n 184, p 23.

²²⁹ For an example of the complexities of a fully sequenced human genome, see that of Craig Venter, available at <<http://huref.jcvi.org/>> last accessed 6/10/09.

²³⁰ Knome Inc, above n 226.

developments in this field occur, it is necessary to consider in advance future protection for such developments.²³¹

3.5 Could pharmacogenomic inventions attract patent protection by way of Swiss-type claims?

Certain pharmacogenomic inventions could be protected by way of Swiss-type claims. Such claims represent a more appropriate form of protection for pharmacogenomic inventions, as they relate to use of the drug itself rather than a genetic sequence. Due to recent approval in New Zealand of the use of Swiss-type claims for new patient groups, it is possible that a known drug with a known use could attract a renewed patent term based on a novel class of patients defined by genome.

(a) The decision in Schering

The IPONZ Guidelines state that for a Swiss-type claim to rely on novelty residing in a new patient group, the requirements from *Medco Research*²³² must be satisfied. However the TBA in *Schering* restricted the requirements from *Medco Research*.²³³ There is some uncertainty as to precisely what the TBA decided and whether this decision will be applied in New Zealand.²³⁴

²³¹ Thank you to Associate Professor Martin Kennedy from the Carney Centre for Pharmacogenomics for his insight concerning the rapid progression of genome sequencing.

²³² *Medco Research*, above n 114; discussed above at para 2.3(a)(ii)(3).

²³³ *Schering*, above n 108, discussed above at para 2.3(a)(ii)(4).

²³⁴ See discussion above at para 2.3(c)(ii).

- (i) A distinguishable new patient group that does not overlap with a known patient group

The first requirement from *Medco Research*, that the new patient group does not overlap with a known patient group, provides a troublesome barrier to patentability by way of Swiss-type claims. New patient groups defined by pharmacogenomic inventions typically relate to the narrowing of a previous patient group (based on increased efficacy or decreased toxicity in that subgroup), rather than application to an otherwise untreated group. The issue in contention therefore is whether New Zealand will follow the approach of the TBA in *Schering* and abandon this requirement for a valid Swiss-type claim.

As discussed at paragraph 2.3(b)(ii), the UK Patent Office Guidelines interpret *Schering* as removing this criterion but state that the UK Patent Office will not follow this approach. In New Zealand, the Assistant Commissioner failed to mention this criterion in *AstraZeneca AB's Application*.²³⁵ It was noted that *Schering* overruled *Medco Research* insofar as the 'functional relationship' requirement is concerned, but whether or not there may now be an overlap between groups was not discussed. This omission was of little significance as the Assistant Commissioner did not conclude whether *Schering* would apply in New Zealand. It was stated that "[e]ven accepting that the second criterion of *Medco*, which appears to be superceded [sic] by *Schering* is applicable, the new patient group is not arbitrary."²³⁶ There is no discussion of *Schering* in the IPONZ Guidelines which were released following *AstraZeneca AB's Application*. The implication of this is that *Schering* will not be followed in New Zealand.

This is a critical issue in determining whether Swiss-type claims can provide protection to pharmacogenomic inventions. The reasoning from *Schering* ought to be adopted in New

²³⁵ *AstraZeneca AB's Application*, above n 123.

²³⁶ *AstraZeneca AB's Application*, above n 123, p 17.

Zealand in order to allow for this application. If IPONZ and the courts reject the TBA's decision in *Schering*, as the UK Patent Office have done, pharmacogenomic inventions will only rarely attract patent protection by way of Swiss-type claims. Generally, the groups will overlap. However if the decision in *Schering* is accepted, there is no reason why pharmacogenomic inventions could not be protected using Swiss-type claims. The potential application of Swiss-type claims to pharmacogenomic inventions therefore provides a justification for adopting the decision in *Schering*.

(ii) Choice of the new patient group must not be arbitrary

The survival of the second *Medco Research* requirement in the EU following *Schering* is contentious. Whether choice of the new group is arbitrary is determined by existence of a functional relationship between the particular physiological or pathological status of this new group and the therapeutic effect obtained.²³⁷ This means the feature identifying the new group of patients must have a real impact on the result of treatment.²³⁸ The Board in *Schering* disagreed with the *Medco Research* Board's interpretation of *Duphar*, but proceeded to distinguish *Medco Research* on the basis that in the case before them, there was a relationship between the functional status of the group and response to treatment. It is therefore necessary to consider whether this requirement would be fulfilled by pharmacogenomic inventions, as even if the decision in *Schering* is accepted, this requirement may still exist.

The purpose of pharmacogenomic research is to identify relationships between the genetic profile of individuals and drug response. Therefore the 'functional relationship' requirement is likely to be easily satisfied. 'Physiology' is defined as the science of the

²³⁷ *Schering*, above n 108, para 8.7.

²³⁸ *Ibid.*, para 8.7.

functioning of living organisms and their component parts.²³⁹ 'Pathological' is defined as the study of disease processes with the aim of understanding their nature and causes.²⁴⁰ Therefore the phrase 'physiological or pathological status of the patient group' refers to identification of the patient group based on the bodily function, diseased or healthy, of the patient group. This phrase has been interpreted as excluding a subgroup of fish which are attacked by sea lice of a specific maturity.²⁴¹ The maturity of the attacking sea lice was held not to have any effect on the functioning of the living organism and thus on the physiological status of the fish. Conversely, in *Queen's University Kingston*, a class of patients defined by their genotype for Factor VIIIIC was considered to be a 'physiological or pathological status'.²⁴² Claims for pharmacogenomic inventions, where patient groups are defined by their genotypes, will therefore likewise fulfil this requirement.

Because both elements of the second *Medco Research* criterion are satisfied by pharmacogenomic inventions, determination of the status of this criterion is therefore not crucial. The problematic aspect is the first criterion. Acceptance of *Schering* by IPONZ is therefore required in order to abandon this requirement and permit the application of Swiss-type claims to pharmacogenomic inventions.

(b) The position in Japan concerning second medical use claims

The proposal to use Swiss-type claims as a form of protection for pharmacogenomic inventions does not appear to have been widely considered. The Examination Guidelines for Patent and Utility Model in Japan, however, include a provision which expressly

²³⁹ Oxford Concise Medical Dictionary (7th ed., Market House Books Ltd, 2007).

²⁴⁰ Ibid.

²⁴¹ T 0708/02 *VERICORE/Sea lice infestation* (Unpublished) 4 April 2006.

²⁴² *Queen's University Kingston*, above n 113; discussed above at para 2.3(a)(ii)(2).

approves of the application of second use claims, where novelty resides in the new patient group, in order to provide patent protection to pharmacogenomic inventions.²⁴³

The Japanese law concerning methods of medical treatment is similar to that of New Zealand and the EU. It is a requirement of patentability in Japan that inventions are 'industrially applicable'. Methods of medical treatment are not considered industrially applicable and therefore a claim in the form 'Use of substance or composition X for the treatment of disease Y' will be excluded from patentability.²⁴⁴

Concerning second medical use inventions, the law is similar to that in the EU following entrance into force of the EPC 2000. No distinction is drawn between first and second medical use inventions. Second medical uses can be claimed directly, in the form 'A medicine for disease Z containing an effective compound A'.²⁴⁵ All product inventions where novelty derives from the new use can be patented. Because of this, Swiss-type claims have never been required in Japan.

The Japanese Examination Guidelines now expressly permit medical product claims where novelty resides in the dosage regime or target group of patients.²⁴⁶ Furthermore, where information concerning drug response is obtained by analysis of genetic

²⁴³ Japan Patent Office Examination Guidelines for Patent and Utility Model in Japan (2005) Part VII: Examination Guidelines For Inventions in Specific Fields, Chapter 3 "Medicinal Inventions", cl 3-3, available at <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/7_3.pdf> last accessed 6/10/09. The Examination Guidelines state that a claimed medicinal invention can have novelty in the following situation:

(3-3)(a) in a case in which a person skilled in the art can clearly distinguish the target patient groups of the claimed invention from those of the cited invention, since it becomes clear that the claimed medicinal invention defined by the above mode of medical treatment is particularly effective to a patient having, for example, a particular gene type, and it becomes clear that the target patient group of the claimed medicinal invention is different from the target patient group which is not specifically specified in the cited invention.

²⁴⁴ I Shimbo, A Cobden and K Sumikura, "The patentability of medicinal inventions related to personalized medicine in Japan" (2005) 23 Nature Biotechnology 1367.

²⁴⁵ Japan Patent Office Examination Guidelines for Patent and Utility Model in Japan, above n 243, Part VII(3)(1.1.2)

²⁴⁶ Ibid., Part VII(3)(2.2.1.1)(3).

polymorphism, patent protection may be conferred by specifying that class of patients.²⁴⁷ There is no restriction in the relevant provision that the newly defined patient group cannot overlap with the prior treatment group.

The Japanese provision therefore represents an interesting practical example of what is proposed in this paper. Providing this enhanced protection to pharmacogenomic inventions in Japan will have a beneficial impact on research strategies of pharmaceutical companies.²⁴⁸

(c) An alternative form of Swiss-type claim which could be employed

There is one further possibility for use of Swiss-type claims in protecting pharmacogenomic inventions. The following claim, modified to fit the New Zealand context (where Swiss form is required), has been proposed by an Australian commentator to avoid inherent issues with gene patents;²⁴⁹

Use of a known compound X in the manufacture of a medicament for use in treating condition Y, where use is comprised of the following steps: (1) testing the patient for the presence of genetic marker Z, (2) correlating the result of that test with an expected drug response, and (3) prescribing drug X accordingly.

Structuring the claim in this manner avoids directly claiming the relevant genetic marker or any means of testing for it. Rather, the claim is directed to using the presence of a

²⁴⁷ Ibid., Part VII(3)(2.2.1.1)(3-3)(a).

²⁴⁸ Shimbo, above n 244, 1369.

²⁴⁹ Altin, above n 221, p 8.

Original form of claim proposed by Altin:

A method for using drug X to treat a patient suffering from condition Y, that method comprising the steps of (1) testing the patient for the presence of genetic marker Z, (2) correlating the result of that test with an expected drug response, and (3) prescribing drug X accordingly.

genetic marker to guide prescription of a drug.²⁵⁰ Novelty resides in the steps for use, including testing for the presence of a genetic marker.

This proposed form is another possible extension of Swiss-type claims. With this form of claim, rather than novelty residing in the new dosage regime, it is found in the use outlined in the three steps. As it is a form of Swiss-type claim, the same objections apply to this form of claim as have been discussed in chapter II. However the benefit of this form of extension is that by focusing on the new use of the drug in association with a genetic test, rather than on use of the drug in a new patient population, the *Medco Research* requirements are avoided. This alternative form of Swiss-type claim should therefore be considered for use in pharmacogenomics.

3.6 A final word on pharmacogenomics

This chapter has reviewed the field of pharmacogenomics and the current patent protection employed in this field. Although concerns with current forms of protection are not pressing, it is beneficial to identify an alternative form of patent protection available. This has been outlined, along with practical limitations of the application of Swiss-type claims in this field. The possibility of using Swiss-type claims in the field of pharmacogenomics will turn on the acceptance and interpretation in New Zealand of *Schering*. Finally, an alternative form of extension of the Swiss-type claim has been proposed based on use of the drug in concert with a genetic test. This may avoid limitations of claims based on new patient groups.

²⁵⁰ Altin, above n 221, p 8.

CONCLUSION

Swiss-type claims have fulfilled an important and useful role in bridging the gap between principles of law and the rapidly evolving pharmaceutical sector. Such claims have been accepted in New Zealand for the past decade, and despite legal and moral objections, they are likely to remain. However, while review of the patent system is in progress, it would be beneficial for the legislature to address this form of claim.

The EU (and the UK) have gone one step further and now permit direct claims for a new therapeutic use of a known compound. Such claims expose practitioners to infringement proceedings, thus nullifying the intention of the methods of medical treatment exclusion. This approach should not be adopted in New Zealand.

Extended Swiss-type claims should continue to be accepted, but clear standards of novelty and inventiveness must be observed and maintained. IPONZ ought to emphasise this to examiners, in order to prevent the over-extension of Swiss-type claims. The requirement of examination for inventive step in the Patents Bill 2008 will help ensure obvious claims are rejected.

One can only speculate about the significance of Swiss-type claims in the emergent field of pharmacogenomics. While existing protection may provide adequate incentives for development at the present time, rapid advances in this field threaten the value of current patent protection of pharmacogenomic inventions. Given recent extensions of the scope of Swiss-type claims, it is possible that such claims could be employed to provide protection to gene-focused drug development. This is an avenue that should be considered by the pharmaceutical industry and regulators alike, in a bid to find a comprehensive yet workable framework of patent protection for the rapidly burgeoning and medically significant field of pharmacogenomics.

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