Patenting Pharmaceuticals? The Impact of a New Zealand Doctrine of Equivalents Following *Actavis v Eli Lilly*

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October 2021

A dissertation submitted in partial fulfilment of the requirements for the degree of Bachelor of Laws with Honours (LLB(Hons)) at the University of Otago

Acknowledgements

First and foremost, I would like to express my sincere gratitude to my supervisor, Dr Jeanne Snelling. Thank you for gently pushing me towards this research topic and for reading pages upon pages of my writing throughout. Thank you for your unwavering support, for your constant belief in me, and for your encouragement to do my best.

Thanks to Mum and Dad, for fielding all of my panicked phone calls. Thank you for reminding me how far I have come and for giving me the final push I needed to compete this research.

Thanks to my friends, and to Zac Arlidge, for believing in my capabilities. Completion of this paper was truly accomplished because of the support system I am constantly surrounded by.

Finally, thanks to Bianca Hawkins, my friend, library companion, and a fellow Honours student. Thank you for working alongside me and for procrastinating with me in the form of online shopping and gossiping about reality TV.

Contents

1.0 Introduction

1.1 Actavis v Eli Lilly and the Status Quo in New Zealand

In the 2017 case of *Actavis v Eli Lilly*[1] (*Actavis*) the United Kingdom Supreme Court (UKSC) unanimously handed down a decision which threw a curveball for patent infringement cases. The decision, which focused on the well-established methods of patent interpretation from *Catnic Components,*[2] *Improver v Remington,*[3] and *Kirin-Amgen*,[4] substantively departed from these decisions in favour of introducing a Doctrine of Equivalents (DoE) into United Kingdom patent law. The recognition of a DoE by the UKSC has enlarged the scope of patent protection in infringement cases. This generates differing views of the Doctrine both positive and negative, as the Doctrine arguably has the potential to undermine the justifications for the entire patent system. These views will be interrogated in this paper.

In New Zealand, patent law is governed by the Patents Act 2013 and the purposive construction approach to patent infringement from *Catnic.* There is currently no recognisable DoE in New Zealand. However New Zealand law is often shaped by United Kingdom law, so the question arises whether New Zealand will soon follow the United Kingdom and establish a DoE in infringement cases.

Actavis[5] concerned a patented anti-cancer treatment drug and an allegedly patent-infringing variant. Eli Lilly owns a UK patent conferring rights to manufacture an anti-cancer medication comprising of pemetrexed disodium and vitamin B12, or a generic substitution of B12.[6] Eli Lilly brought infringement proceedings alleging that Actavis, a competing pharmaceutical company, was infringing its patent either directly or indirectly with its own variant of a cancer treating medicament.[7] The UKSC *Actavis* decision has several implications for the development of therapies in the healthcare industry. Pharmaceutical companies seeking patentability for therapies in the UK can now rely on the DoE to expand the scope of their

[1] *Actavis UK Ltd and others v Eli Lilly and Company* [2017] UKSC 48.
[2] *Catnic Components Ltd and Another v Hill and Smith Ltd* [1982] RPC 183 (UKCA).
[3] *Improver Corp v Remington Consumer Products Ltd* [1982] RPC 69 (UKCA).
[4] *Kirin-Amgen Inc and others v Hoechst Marion Roussel Ltd and others* [2005] 1 All ER 667 (HL).
[5] *Actavis,* above n 1.
[6] *Actavis,* above n 1, at [4].
[7] At [8].

patent, encompassing infringing variants, and claiming a large monopoly to the detriment of other innovating pharmaceutical companies.

In an industry that relies heavily on generic pharmaceutical substitutions, the healthcare sector could become adversely affected by the introduction of Equivalents into patent infringement cases. Given the DoE expands a patent holder's monopoly significantly, I will consider the implications of a DoE through the lens of established patent law principles to determine whether New Zealand should adopt a DoE.

1.2 The Focus of This Dissertation

This dissertation aims to evaluate the implications of a potential for a New Zealand DoE in patent infringement cases following *Actavis*. This chapter sets out the relevance of *Actavis*, the status quo of patent law in New Zealand, what this dissertation will cover, and finally, it will introduce you to the concept of a patent. Chapter Two provides an explanation of patent law theory, a historical account of patent law, and the New Zealand Patents Act 2013. Chapter Three then examines three historic cases that have influenced patent infringement interpretation; those being – *Catnic, Improver* and *Kirin-Amgen*. Chapter Four explains the concept underlying the DoE, before analysing the *Actavis* decision and its significance. Chapter Five then investigates jurisdictions that have been early adopters of the Doctrine and why they adopted the Doctrine, including the US, Germany and France. It also analyses the Australian and Singapore approaches to patent infringement interpretation following *Actavis*. Since *Actavis*, Australia and Singapore have also considered whether they should adopt a DoE for the first time. Chapter Six explains the status quo in New Zealand and examines the potential for a New Zealand DoE. Applying the principles of patent law, Chapter Six will consider the strengths and weaknesses of the arguments for adopting the Doctrine and will finely balance these arguments with arguments against the Doctrine. I will assert that the arguments against adopting a DoE in New Zealand are far stronger than the arguments for adopting a DoE. Chapter Six will further analyse the potential impact of Equivalents on the costs of developing pharmaceuticals and therapies in New Zealand and the follow on effects that this will have on affordable healthcare in New Zealand.

1.3 Introduction to a Patent

Patent law is an intricate web of rules and criterion. As part of the intellectual property class, a patent confers personal property rights upon the owner.[8] For the duration of patent registration, the owner is the patentee of that patent, unless they choose to sell their patent which has the effect of transferring their title to a third person.[9]

A patent can be granted in relation to a process, a product, biotechnology, and electrical and computer apparatus among other things.[10] This affords the patentee the absolute right to develop, manufacture, and sell their invention to the exclusion of others for a limited time period of 20 years.[11]

Patents are intrinsically economic,[12] granting a limited monopoly to certain innovators who meet patentability criteria.[13] Broadly speaking, patents are granted for "true patent inventions" that can be described as "new manners of manufacture" as per the United Kingdom Statute of Monopolies 1623.[14]

[8] Susy Frankel and Jessica C Lai *Patent Law and Policy* (LexisNexis Wellington, 2016) at 7.
[9] Paul Sumpter *Intellectual Property Law: Principles in Practice* (3rd ed, CCH New Zealand, Auckland, 2017) at 309.
[10] Sumpter, above n 9, at 279.
[11] Patents Act 2013, s 20(1).
[12] Frankel and Lai, above n 8, at 7.
[13] See discussion of patentability criteria in chapter 2.3.
[14] Patents Act, s 6.

2.0 Theory of Patent Law

2.1 The Justifications for Patent Law

The patent system exists for the mutual benefit of both inventors and society in that it attempts to balance incentives for innovation with societal benefits of inventions being publicly available. Successfully registering a patent under the Patents Act 2013 confers upon the patentee a limited right to exclusively produce the subject matter of the patent.[15] In return for the innovative exclusivity that a patent bestows upon a patentee, the features of the invention must be publicised. This public disclosure facilitates the general understanding of the patent scope, allowing others to innovate around the patent or improve upon the invention after patent expiration.[16]

The law allows for workable patent systems because at its core, patent protection provides inventors with an incentive to invest time, money and energy into researching and developing inventions, with the confidence that their work will not be exploited by their competitors.[17] It is well-accepted, albeit largely presumptive, that without this property protection, inventors will be less inclined to innovate, fearful that third-parties will replicate their invention at a lower cost, and capitalize on their hard work.[18] It is also feasible that a lack of protection will prevent inventors from disclosing the details of their inventions, and society will be unable to benefit from the invention being publicly available.[19]

The incentive to invent is also substantially connected to the societal benefits of inventions being publicly available. A patentee can disclose their invention to the public, giving the public an opportunity to utilise that invention, and a patentee can be confident that the patent system will protect them from the exploitation of other inventors throughout the duration of patent registrability.[20] In that sense, there is a mutual benefit to inventors and society alike, both profiting from the fruits of inventive labour.

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[15] Sumpter, above n 9, at 271.
[16] At 271.
[17] At 271.
[18] Above n 5, at 14.
[19] Above n 6, at 272.
[20] Above n 5, at 15.

Patents embody economic qualities,[21] which Cooke J reiterated in *Wellcome Foundation Ltd v Commissioner of Patents* when he said that "the national economic interest lies at [the] heart" of patent law development.[22] The patent system confers on patentees a limited monopoly right over their invention.[23] The extent of the economic value and the subsequent monopolistic feature of a patent is determined by the scope of that patent protection.[24] A wider patent scope will grant patentees a more extensive monopoly than would be afforded to patentees with narrow patent scope.[25]

Patents can appropriately be characterized as the intellectual property right that affords its owners the most robust monopoly protection.[26] For that reason, patent protection that is too broad will fail to adequately balance the dual objectives of patent law just as equally as patent protection that is too scarce will fail to uphold the rationales of patent law. If the scope of a patent is too broad, enabling stronger patent protection, then a patentee will hold a large monopoly to the detriment of other inventors.

The patent register is a core legal mechanism that regulates patents in New Zealand. The legislated rationales for the patent register[27] reflect the justifications for a patent system because the patent register essentially exists to facilitate the public's knowledge of what patents are in force, who the patentee is, the scope of their patent and any other information relevant to the patent.[28]

2.2 The Statute of Monopolies

To appreciate why the patent system was introduced, it is essential to go back to 16th and 17th century England. The Statute of Monopolies was enacted to address an escalating economic problem created by the Crown in the early 17th century. At that time, the monarchy was abusing its monopoly-granting prerogative by granting monopolies as consideration for unwavering

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[21] Frankel and Lai, above n 8, at 7.
[22] *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA) at 389 and 391, n 4 as cited in Frankel and Lai, at 8.
[23] Frankel and Lai, above n 8, at 7.
[24] Robert P Merges and Richard R Nelson "On the Complex Economics of Patent Scope" (1990) 90(4) CLR 839 at [1].
[25] At [1].
[26] Susan Frankel and Geoff McLay *Intellectual Property in New Zealand* (1st ed, LexisNexis Butterworths, Wellington, 2002) at 324.
[27] Patents Act, s 195.
[28] Frankel and Lai, above n 8 at 15, citing Patents Act 2013, s 195.

loyalty to the Crown,[29] protecting inventions and industries to an intolerable extent.[30] Monopoly protection even extended to "many of the necessities of life", and "monopolists were very oppressive in the enforcement of their rights".[31] Also, items such as playing cards were patented in 16th century England, creating a "monopoly illegal at common law".[32] Parliament passed the Statute to prevent the Crown from granting these limitless monopolies. An exception to this prohibition was legislated, allowing the Crown to grant monopolies for real patent inventions that could be described as "manners of new manufacture".[33]

The concession that the Statute of Monopolies was the first manifestation of patent law is a mere fiction. The essence of patent law today was first recognized by Elizabeth I who constructed and enforced a workable "patent system" during her reign in the 16th century.[34] *Darcy v Allin* was later heard in 1601,[35] effecting the beginning of a common law patent system.[36] Another historical case of great significance that predated the Statute of Monopolies is Matthey's case[37] which largely stated that the object of patent law is to protect unprecedented inventions.[38]

The Statute has been described by some scholars as a form of political peace-making,[39] shaping patent law as it exists today, and still bearing reference in New Zealand patent legislation.[40] King James and Parliament reached a compromise, James agreeing to a legislative solution to address the patent problem in exchange for financial aid.[41] There was also a number of internal compromises, with the two Parliamentary Houses agreeing to legislate the Statute of Monopolies while maintaining a small number of pre-existing patents.[42] These compromises

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[29] Frankel and Lai, above n 8, at 89.
[30] Jarratt William "English Patent System" (1944) 26(11) JPOS 761 at 761.
[31] Thomas A. Hill, "Origin and Development of Letters Patent for Invention," (1924) 6 J. Pat. Off. Soc'y 405, at 407, n 78 as cited in Sa Yu "Political Privilege, Legal Right, or Public Policy Tool? A History of the Patent System" (2009) ATRIP 1 at 21.
[32] Thomas A. Hill, "Origin and Development of Letters Patent for Invention," (1924) 6 J. Pat. Off. Soc'y 405, at 407, n 89 as cited in Yu, above n 31, at 23.
[33] Statute of Monopolies 1623 (UK), s 6.
[34] E Wyndham Hulme "History of the Patent System Under the Prerogative and at Common Law" (1896) 12(2) LQR 141 at 144.
[35] *The Case of Monopolies* (1601) 77 ER 1260 (CKB).
[36] Hulme, above n 34 at 151.
[37] Date of origin unknown.
[38] Hulme, above n 34 at 152.
[39] Chris Dent "'Generally Inconvenient': The 1624 Statute of Monopolies as Political Compromise" (2009) 33(2) MULR 415 at 438.
[40] Patents Act, s 14.
[41] Dent, above n 39, at 452.
[42] At 452.

contributed to a legislative system that was, in its most simplified state, passed to prevent the creation of unjustified monopolies while still protecting innovative originality and any resulting economic development.[43] This quality of historical patent legislation is the foundation of current patent law in New Zealand.

2.3 New Zealand Patent Law and the Patents Act 2013

New Zealand patent law is currently regulated by the Patents Act 2013 (the Act). Replaced by the 2013 Act, the previous 1953 Act was materially modelled from the Patents Act 1949 (UK),[44] and was interpreted using case law from the United Kingdom. The 2013 Act is also interpreted with reference to United Kingdom patent cases, and the New Zealand approach to patent infringement interpretation is derived from high profile United Kingdom cases.[45]

The practice of patenting an "invention" under the Act can be used for a wide variety of inventive concepts,[46] though the variety of patentable inventions is not expressed within the Act.[47] Most commonly, a new product or process can be patented, or an improved version of either of those aforementioned matter.[48] Other patentable inventions include, but are not limited to, biotechnology, electronic appliances and computer machinery.[49]

Patentability criteria is governed by s 14 of the Act. Section 14 states:

> An invention is a patentable invention if the invention, so far as claimed in a claim, –
> (a) Is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
> (b) When compared with the prior art base –
> (i) Is novel; and
> (ii) Involves an inventive step; and
> (c) Is useful; and
> (d) Is not excluded from being a patentable invention under section 15 or 16.

[43] Sumpter, above n 9, at 279.
[44] Ian Finch *James & Wells Intellectual Property Law in New Zealand* (online ed, Thomson Reuters, 2017) at 9.
[45] See chapters 3.4 and 6.1 for further discussion on the New Zealand approach to infringement interpretation.
[46] Sumpter, above n 9, at 278.
[47] At 279.
[48] At 278.
[49] At 279.

2.3.1 Novelty

The novelty and inventive step requirements are assessed in relation to the prior art base,[50] which the Act defines as all material (a product, a process or otherwise) that has been publicly communicated within New Zealand or worldwide either in writing, orally, by its physical use or in any other manner.[51] Therefore, to be eligible for patentability an invention must be new in the sense that it is not already existing knowledge.[52]

2.3.2 Inventive Step

The term "inventive step", often interchanged with "non-obviousness", requires that an invention seeking patentability must not be so foreseeable that a person with knowledge in that particular art would find the invention obvious.[53] The inventive requirement is also analysed from the prior art base.[54]

2.3.3 Utility

The Act requires that an invention seeking patent registration must be "useful",[55] the definition of which is an invention with "specific, credible and substantial utility".[56]

To facilitate public understanding of whether something is patentable, the Act helpfully provides a list of matter that is excluded from patentability. Section 15 excludes from patentability inventions that, if capitalized upon, would conflict with 'public order or morality' according to operative New Zealand law. The Act provides several examples of matter that would be covered by this section, including an inventive process for the purpose of cloning humans.[57] Section 16 excludes specific subject-matter from patentability, including human beings and related biological processes, surgical or therapeutic treatment procedures, diagnostic procedures on human beings, and plant varieties as covered in s 2 of the Plant Variety Rights Act 1987.

[50] Patents Act, s 14.
[51] Section 8.
[52] Sumpter, above n 9, at 285.
[53] Sumpter, above n 9, at 287.
[54] At 287.
[55] Section 14.
[56] Section 10.
[57] Section 15.

New Zealand also has obligations under a number of international patent regimes, contributing to the increased harmonisation of patent law systems worldwide.[58] The 2013 Act noticeably strays from United Kingdom patent legislation,[59] creating a uniquely New Zealand approach to patents. In saying that, the New Zealand patent regime abides by international standards in discrete ways, including by adopting language from provisions in the European Patent Convention in the 2013 Act.[60]

New Zealand is a signatory to both the Patent Cooperation Treaty (PCT)[61] and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[62] The PCT created an international regime that facilitates the filing of a single application by an innovator. Filing this one application gives the inventor's application effect in all of the signatory states to the PCT, short of granting the applicant a patent.[63] The TRIPS agreement provides that member states must impart patent protection upon inventions that are new, inventive, and are qualified for industrial protection, and as such, any signatory that falls behind may face punitive action from the World Trade Organisation.[64]

[58] Sumpter, above n 9, at 273.
[59] Frankel and Lai, above n 8, at 22.
[60] Frankel and McLay, above n 26, at 323.
[61] Patent Cooperation Treaty 1160 UNTS 231 (opened for signature June 19 1970, entered into force April 2002) ("PCT") <www.wipo.int>.
[62] Agreement Establishing the World Trade Organisation, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights 1869 UNTS 299 (opened for signature 15 April 1994) ("TRIPS Agreement") <www.wto.org>.
[63] Sumpter, above n 9, at 274.
[64] Sumpter, above n 9, at 274.

3.0 History of Patent Law

This section explains the interpretive approaches to patent law that have been established by the courts and the current interpretive approach to patent infringement in New Zealand. In particular, three English cases have respectively paved the way of patent infringement interpretation in New Zealand; these cases are *Catnic Components v Hill & Smith*,[65] *Improver v Remington*,[66] and *Kirin-Amgen Inc v Hoechst*.[67]

3.1 Catnic Components and Purposive Construction

Lord Diplock and the House of Lords in *Catnic,*[68] a late-20th-century patent case, developed a cardinal rule for interpretation of patent infringement cases.[69] This judge-made rule involves purposively constructing a patent claim to determine whether or not a competitor has breached a pre-existing patent whilst developing a variant of their own.[70]

In *Catnic*, the patent at the centre of proceedings was one registered by Catnic for steel lintels, a horizontal metal sheet that extends over a door or a window.[71] Catnic's first patent claim stated that the support arm at the back of the lintel was to "extend vertically" from the base of the invention, forming a "perpendicular" angle.[72] The defendants, Hill & Smith Ltd, manufactured a variant of Catnic's patented lintel that, rather than extending at a 90° angle from the base, extended about 6-8° from vertical.[73] This variance altered the function of the lintel to a trivial extent,[74] but did not breach the plaintiff's patent claim in the literal sense.[75] However, Lord Diplock noted that despite "vertical" being an unambiguous expression, context is imperative.[76] While some occupations require the use of precise language, it is unnecessary and indeed unlikely for lintels used by tradesmen to be exactly 90°, as long as the lintels are

[65] *Catnic*, above n 2.
[66] *Improver*, above n 3.
[67] *Kirin-Amgen*, above n 4.
[68] *Catnic*, above n 2 per Lord Diplock (HL).
[69] Frankel and Lai, above n 8, at 248.
[70] *Catnic*, above n 2, at 243 per Lord Diplock (HL).
[71] *Catnic*, above n 2, at 183 per Lord Diplock (HL).
[72] At 184.
[73] At 184.
[74] At 184.
[75] Frankel and Lai, above n 8, at 249.
[76] *Catnic*, above n 2, at 244 per Lord Diplock (HL).

close enough to sufficiently perform the required function.[77] Consequently, applying a purposive approach would find that Hill & Smith Ltd infringed Catnic's patent with their variant.[78]

Prior to *Catnic*, infringement cases were approached using a literal interpretation of a patent claim, and a distinct consideration of whether a variant substantively produced the essence of a patent.[79] This was commonly referred to as the "pith and marrow" of the patent, as devised by Lord Cairns.[80] These separate causes of action were consolidated into one purposive approach by the House of Lords in *Catnic* which held that separating infringement issues was a catalyst for confusion.[81]

The all-in-one purposive approach adopted by the House of Lords naturally broadens the scope of patent protection. Variants that differ from a patent in an immaterial way will also breach the patent.[82] Applying a purposive approach to patent infringement requires analysing the words of a patent claim in light of the innovator's purpose as ascertained from the patent in its entirety.[83] Their Lordships held that Hill & Smith Ltd's variant was "vertical" for the purposes of being encompassed by Catnic's patent due to its trivial functional difference.[84]

3.2 Improver and the Introduction of the Improver Questions

In *Improver v Remington*[85] Hoffman J polished the "purposive construction" test coined by the House of Lords in *Catnic*. In doing so, he formulated three questions that courts should review to aid their purposive reading of patent claims.[86] These questions have since achieved recognition as the "*Improver* questions" or the "protocol questions".[87] Hoffman J sets them out as:[88]

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[77] *Catnic*, above n 2, at 244 per Lord Diplock (HL).
[78] Frankel and Lai, above n 8, at 249.
[79] At 249.
[80] Frankel and Lai, above n 8, at 249, citing *Clark v Adie* (1877) 2 App Cas 315 (HL) at 320.
[81] *Catnic*, above n 2, at 242 per Lord Diplock (HL).
[82] Frankel and Lai, above n 8, at 250.
[83] Frankel and McLay, above n 26, at 357, citing *3M v Plastus Kreativ* [1997] RPC 737, 743 (EWHC).
[84] Crawford Jamieson "In Defence of a UK Doctrine of Equivalents" (2019) 41(3) EIPR 147 at 148.
[85] *Improver*, above n 3.
[86] *Improver*, above n 3, at 189.
[87] Frankel and McLay, above n 26, at 357.
[88] *Improver*, above n 3, at 189.

(1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no –
(2) Would this (ie that the variant had no material effect) have been obvious at the date of the publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes –
(3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

If, however, question three was answered in the negative then the variant is caught by the patent claim and will be found to be infringing the patent. In this instance it is clear that the patentee intended the claim description to be purely symbolic, providing the most fitting representation of the class.[89]

Questions one and two of the reworked purposive test are factual inquiries that can only be answered with reference to both the patent claim and the variant.[90] Question three is a question of law which examines whether the wording of the claim would be interpreted by the person skilled in the art in such a way that the variant would be outside the claim.[91]

Improver[92] concerned the "Epilady", a hair-removal instrument invented by Improver Corporation. Improver's "Epilady" functioned by the use of a revolving "helical spring" that extracted hairs as the device was maneuvered over the body.[93] Remington manufactured a device that removed hair in a similar way to the "Epilady", however, Remington's invention notably incorporated the use of a rubber rod to achieve this similar end.[94] Hoffman J and the court in *Improver* developed the "*Improver* questions" to assist them in purposively determining whether Remington's variant infringed Improver's patented "Epilady". The court held that Remington's hair removal device did not infringe Improver's patent on the basis that "the rubber rod is not an approximation to a helical spring. It is a different thing which can in limited circumstances work in the same way".[95] Improver's claim was unsuccessful, with

[89] At 189.
[90] David Koedyk "*Actavis* in the Antipodes – A doctrine of equivalents for New Zealand?" (2018) IPSANZ at 5.
[91] At 5.
[92] *Improver*, above n 3.
[93] Koedyk, above n 90, at 4.
[94] At 4.
[95] *Improver*, above n 3, at 197.

Remington successfully evading an infringement finding against them due to Improver's failure to satisfy the third limb of the *Improver* questions.

3.3 Kirin-Amgen and the Rejection of a UK Doctrine of Equivalents

In the early 2000s, the House of Lords in *Kirin-Amgen* reaffirmed the *Catnic* purposive approach to claim construction in infringement cases.[96] The House of Lords per Lord Hoffman observed that the meaning of the claim is that which the person skilled in the art would derive from the words of the patent specification, from an objective and contextual perspective.[97]

The House of Lords next considered whether as in the United States, a United Kingdom DoE was necessary. The Doctrine works by extending the patent scope to embrace technologies that "perform 'substantially the same function in substantially the same way to obtain the same result' as the patented invention".[98]

Such inquiry was required because in the time since *Catnic* was decided in the House of Lords, article 69 of the European Patent Convention (EPC),[99] a treaty to which the United Kingdom is a member state, was drafted and set to come into force.[100] Article 69 and the Protocol on interpretation of article 69 are both incorporated into United Kingdom patent legislation,[101] "prevent[ing] equivalence from extending outside the claims",[102] yet still enabling it to form part of the contextual background required for the inquiry conducted by the person skilled in the art.[103] This is reaffirmed in the later addition of article 2 of the EPC, but in any event does not allow protection beyond the confines of the claims, effectively preventing a United Kingdom DoE.[104] Articles 69(1)[105] and 2(2)[106] of the EPC state:

Article 69

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[96] *Kirin-Amgen,* above n 4, at [33].
[97] At [32].
[98] Machine Co. v Murphy, 97 U.S. 129, 125 (1878), n 124 as cited in Shayana Kadidal "Plants, Poverty, and Pharmaceutical Patents" (1993) 103 YLJ 223 at 248.
[99] European Patent Convention on the Grant of European Patents (European Patent Convention, EPC) 1065 UNTS 199 (adopted 5 October 1973, entered into force 7 October 1977).
[100] *Kirin-Amgen*, above n 4, at [44].
[101] Patents Act 1977 (UK), ss 60 and 125.
[102] *Kirin-Amgen*, above n 4, at [49].
[103] At [49].
[104] *Kirin-Amgen*, above n 4, at [44].
[105] EPC, above n 99, at Art 69(1).
[106] EPC, above n 99, at Art 2(2).

(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

…

Article 2

(2) The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless otherwise provided in this Convention.

The House of Lords also endorsed the *Improver* questions, but commented that the questions are "…only guidelines, more useful in some cases than in others".[107] The Court also compared the status of the *Improver* test to the *Catnic* approach, noting that while the *Improver* questions are insufficient in some instances, purposive construction "…is the bedrock of patent construction, universally applicable".[108]

The approach that developed from *Catnic*, *Improver*, and *Kirin-Amgen* developed in light of the EPC and was accepted as the appropriate approach to patent infringement interpretation before *Actavis* was heard. The approach consisted of purposive construction as coined in *Catnic*, supplemented by the three *Improver* questions.

3.4 The Current New Zealand Approach

When *Catnic* was heard in the House of Lords, New Zealand patent law was governed by the 1953 Act, which largely mirrored the UK patent law under which *Catnic* was decided.[109] Despite a number of legislative changes to patent law in both the United Kingdom and New Zealand, the "purposive construction" approach originating in *Catnic* still remains the approach to infringement in New Zealand under the 2013 Act.

Frankel and McLay indicated at a strong likelihood that New Zealand Courts would follow the United Kingdom approach and apply the *Improver* questions in New Zealand infringement cases,[110] however, this has largely failed to come to fruition. In *Peterson Portable Sawing*

[107] At [52].
[108] At [52].
[109] Frankel and McLay, above n 26, at 356.
[110] Frankel and McLay, above n 26, at 357.

Systems Ltd (in liq) v Lucas[111] the New Zealand Supreme Court omitted the *Improver* test from its infringement analysis, and in fact neglected to mention the *Improver* questions in any capacity.[112] Gault J on behalf of the Supreme Court, noted that "a patent specification is to be read as a whole and given a purposive construction.[113] It must be construed as it would be understood by the appropriate addressee – a person skilled in the relevant art".[114]

Ten years later in the case of *Assa Abloy v Allegion*[115] the High Court referenced and used the *Improver* test, discussing and applying the first two questions, but neglected to consider the third question.[116] The Court determined that the only matter in which the third *Improver* question would be relevant did not require consideration of that question in order to be adequately addressed.[117]

Both *Peterson v Lucas* and *Assa Abloy* illustrate variable responses to the *Improver* questions in New Zealand. On the one hand, the New Zealand Supreme Court has completely overlooked *Improver*, while the High Court, a lower court, has utilised the *Improver* test to some degree. In saying that, *Assa Abloy* was decided no less than 10 years after *Peterson v Lucas*, in 2016, indicating that New Zealand may see more of the *Improver* questions in future patent infringement cases. What *Assa Abloy* establishes is that purposive construction remains the principal approach to infringement cases in New Zealand.[118]

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[111] *Peterson Portable Sawing Systems Ltd (in liq) v Lucas* [2006] NZSC 20, [2006] 3 NZLR 721.
[112] Frankel and Lai, above n 8, at 252.
[113] Terrell on the Law of Patents (16 ed 2005) at [6-101] et seq. as cited in *Peterson v Lucas,* above n 111, at [26].
[114] *Peterson v Lucas*, above n 111, at [26].
[115] *Assa Abloy New Zealand Ltd v Allegion (New Zealand) Ltd* [2016] NZHC 1738.
[116] Koedyk, above n 90, at 13.
[117] At 13.
[118] *Assa Abloy*, above n 115, at [23], citing Catnic Components Ltd and Anor v Hill and Smith Ltd [1982] RPC 183 (HL) at 242.

4.0 Actavis v Eli Lilly in the UKSC

4.1 Introduction

By formally introducing a DoE into UK patent interpretation, *Actavis* has changed the method of interpretation used for determining patent infringement, broadening the scope of patents in favour of patentees. This chapter begins with a brief overview of the DoE, including why it developed, what the Doctrine does, and an example of how the Doctrine works. A discussion of *Actavis* in the UKCA and UKSC, and the significance of the UKSC decision for patent law in general, follows.

4.2 A Brief Overview of the Doctrine of Equivalents and its Origins

The DoE is a judicially developed,[119] equitable doctrine.[120] The Doctrine was developed to address the perceived inadequacies of patent interpretation, whereby a vast number of cases had been held to be non-infringing upon patented technologies based on the wording of the claims, yet were functionally the same as a patented technology.[121] In this situation, the Doctrine works by extending the patent scope to embrace such equivalent variants, technically affording the patentee more protection than their patent initially enabled.[122]

The role of the Doctrine is helpfully set out in *International Nickel v Ford Motor Company*, a 1958 case that applied an Equivalents Doctrine and established a finding of patent infringement.[123] In that case Ford Motor was held to have infringed International Nickel's patent via application of the DoE, after its variant invention fell outside the literal scope of International Nickel's patent claims.[124] International Nickel's patent encompassed a composition of melted iron and magnesium at a rate of "'about 0.04% as a minimum'" to create "'nodular iron'".[125] Ford Motor then began making nodular iron using 0.02% of magnesium, less than International Nickel's minimum threshold of magnesium. Even though there was no

[119] Jamieson, above n 84, at 147.
[120] George M Sirilla, Thomas P Feddo & Michael C Antone "The Doctrine of Equivalents: Both a Sword and a Shield" (2003) 13 FCBJ 75 at 77.
[121] Merges and Nelson, above n 24, at 853.
[122] Jamieson, above n 84, at 147.
[123] Merges and Nelson, above n 24, at 853.
[124] Merges and Nelson, above n 24, at 853.
[125] Merges and Nelson, above n 24, at 853.

infringement on a literal approach, the DoE provided a mechanism for finding patent infringement by Ford.[126]

The exact function of the DoE is eloquently expressed by Judge Learned Hand in the 1948 US case *Royal Typewriter v Remington Rand*:[127]

> [A]fter all aids to interpretation have been exhausted, and the scope of the claims has been enlarged as far as the words can be stretched, on proper occasions courts make them cover more than their meaning will bear.

A "proper occasion" being one where a variant technology uses the same method as the patented product or process to achieve the same outcome as the patented technology, despite all other differences between the two inventions.[128] So, engaged when a variant cannot literally breach a patent by breaching the words of a patent's claims, the DoE presents a middle ground between the objective of creating precise and certain patent claims, and on the other hand, protecting patentees from unsolicited breaches of their patent by competitors.[129] On the contrary, Equivalents often works to excessively broaden the scope of a patent after a patentee has applied for registration of relatively narrow patent claims in order to satisfy the novelty requirement for patentability. A patentee will later use the DoE to claim a larger monopoly to the detriment of fellow inventors, undermining the equitable foundations of the Doctrine in practice.[130] Consequentially, a wealth of uncertainty surrounds the use of the DoE.[131]

Rather than remedying the supposed inequities within various patent systems, the DoE has thus far merely heightened patentee protection, therefore further contributing to incentivizing patentees and disincentivizing third party competitors.[132] Moreover, the force of the DoE grows stronger with each case that applies the Doctrine, and equally, the reasons for using the Doctrine are straying further away from its original intent. Now, the DoE is not only used to remedy the situation where a competitor essentially copies a patented technology, but is also

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[126] Merges and Nelson, above n 24, at 853.
[127] Royal Typewriter Co. v. Remington Rand, Inc.,168 F.2d 691, 692, 77 U.S.P.Q. (BNA) 517, 518 (2nd Cir.), n 59 as cited in Merges and Nelson, above n 24, at 853.
[128] Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 85 U.S.P.Q. (BNA) 328, 330 (1950) (quoting Machine Co. v. Murphy, 97 U.S. 120 (1877)), n 60 as cited in Merges and Nelson, above n 24, at 853.
[129] Joseph S Cianfrani "An Economic Analysis of the Doctrine of Equivalents" (1997) 1 VJLT 1 at [29].
[130] Antonia Kendrick "Actavis v Eli Lilly: Patent Medicine, Risk of Side Effects" (2019) OULJ 44, at 58.
[131] Jamieson, above n 84, at 153.
[132] Natalie Sturicz "Phillips v AWH, Corp., A Doctrine of Equivalents Case?" (2008) 12 MIPLR 385 at 395.

drawn upon "in the event of drafting errors, in the event language proved inadequate to capture their ideas, or in the event that they were simply unable to foresee an after-arising equivalent".[133]

4.3 What Happened in Actavis v Eli Lilly?

The *Actavis*[134] litigation concerned a patented anti-cancer treatment drug and an allegedly patent-infringing variant. Eli Lilly and Company, an American pharmaceutical company, is the owner of a UK patent granting it rights to manufacturing an anti-cancer medication comprising of pemetrexed disodium and vitamin B12, or a generic substitution of B12.[135] Eli Lilly brought infringement proceedings, alleging that Actavis, a competing pharmaceutical company, was infringing its patent either directly or indirectly with its own variant of a cancer treating medicament.[136] Like Eli Lilly, Actavis's prospective medicaments were also pemetrexed and vitamin B12 combinations. But rather than using one specific pemetrexed salt (pemetrexed disodium) as Eli Lilly's patent protects, Actavis's product uses different pemetrexed salts (ditromethamine or dipotassium) or a pemetrexed acid (diacid).[137]

To resolve this dispute, the court considered historic English patent cases to determine the correct approach to patent infringement claims. The UKSC stated that "any patent system must strike a balance between…two competing factors…namely 'a fair protection for the patent proprietor [and] a reasonable degree of legal certainty for third parties'".[138]

Eli Lilly's patented medicament resolves the issue of the potentially life-threatening side effects cancer patients are exposed to when pemetrexed alone is administered.[139] Eli Lilly's patent has existed for some years now, and its existence has enabled successful widespread production and distribution of the patented medicament for the purpose of treating cancer.[140] As such, Eli Lilly's property rights must be balanced with a reasonable degree of certainty for Actavis in producing variants of Eli Lilly's medicament.

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[133] Sturicz, above n 132, at 397-398.
[134] *Actavis,* above n 1.
[135] *Actavis,* above n 1, at [4].
[136] At [8].
[137] At [8].
[138] Protocol on the Interpretation of Article 69 EPC, at Art 1 as cited in *Actavis* (SC), above n 1, at [53].
[139] *Actavis*, above n 1, at [3].
[140] At [3].

Essential to the resolution of *Actavis*, as with any patent infringement case, were the patent claims. Claim one was drafted rather specifically, and as such, reads:

> 1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof [which it then specifies].

The Court of Appeal identified two issues of construction in *Actavis*.[141] The first issue related to the alleged direct infringement of Eli Lilly's patent, and was whether patent protection is confined only to pemetrexed disodium.[142] The second issue concerned indirect infringement of the patent, and whether Eli Lilly's patent restricted the use of pemetrexed disodium in its solid form only, as Actavis argued.[143] In its decision, the Court of Appeal referenced *Catnic*, *Improver* and *Kirin-Amgen*, utilizing purposive construction supplemented by the *Improver* questions in coming to its decision concerning direct infringement. The *Improver* questions are:[144]

> (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no –
> (2) Would this (ie that the variant had no material effect) have been obvious at the date of the publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes –
> (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

Floyd LJ for the Court of Appeal found in favour of Eli Lilly in regard to the first *Improver* question, noting that it is "common ground that the variants represented by the various Actavis

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[141] *Actavis UK Ltd and others v Eli Lilly & Company* [2015] EWCA Civ 555, [2016] 4 All ER 666.
[142] *Actavis* (EWCA), above n 141, at [61].
[143] At [61].
[144] *Improver*, above n 3, at 189.

AIs have no material effect on the way the invention works".[145] However Eli Lilly failed to convince the Court that Actavis's variant satisfied the second and third *Improver* questions. Consequently, Floyd LJ held that Actavis did not directly infringe Eli Lilly's patent.[146]

In respect of the second *Improver* question, Floyd LJ stated that if the person skilled in the art cannot anticipate that a variant will work sufficiently as an alternative to the invention, then it is clear that the variant is not obvious to the person skilled in the art. Thus, they are unable to conclude that "…the variant would have no material effect on the way the invention works".[147]

Floyd LJ concluded that it is clear from the patent claims and in the context of the specification[148] that Eli Lilly intended strict compliance with the language it adopted.[149] At [72] Floyd LJ gave his reasons for answering the third *Improver* question in favour of Actavis:

i) … [Eli Lilly's] specification contains certain passages where the invention is described in very general "class" terms and others where the invention is clearly limited to pemetrexed disodium. When the reader comes to the claims, therefore, he or she will appreciate readily that the patentee has chosen to claim narrowly and by reference to a single chemical, and not broadly by reference to any class.

ii) Pemetrexed disodium is a highly specific chemical compound. Putting aside for present purposes the precise form in which the compound is present, there is no obvious leeway as a matter of language for giving it a broad as opposed to a narrow construction.

iii) The only escape from the above would be to say that pemetrexed disodium would be understood by the skilled person to be used in a figurative sense, so as to denote the best-known member of a class. It is true that sodium is a well-known and perhaps the best-known counter ion for use in circumstances such as these. But if the claim is not

[145] *Actavis* (EWCA), above n 141, at [63].
[146] *Actavis* (EWCA), above n 141, at [80].
[147] *Actavis* (EWCA), above n 141, at [71].
[148] At [73].
[149] At [72].

limited to the sodium salt, there are great difficulties in ascertaining what the class might be. …

iv) The only data contained in the specification are for pemetrexed disodium, and broader claims therefore lack support and might have been unacceptable to the EPO.

v) Importantly, there is a striking contrast between this very specific language and the general terms used in the claim for the methyl malonic acid lowering agent (any "pharmaceutical derivative") and the folic acid components (any "physiologically available salt or ester thereof") which the skilled reader could not fail to notice.

vi) The skilled reader would have understood that there are plausible reasons why the patentee might have wished to limit to the disodium salt. …

Despite the Court of Appeal concluding there was no direct infringement of Eli Lilly's patent, Floyd LJ for the Court found that Actavis *indirectly* infringed Eli Lilly's patent because pemetrexed disodium is utilised in the Actavis products prior to their use.[150]

On appeal, the Supreme Court provided a comprehensive judgment in which it discussed the accepted approaches to infringement interpretation, including explanations of *Catnic, Improver* and *Kirin-Amgen*, but notably diverged from those accepted practices, as is its prerogative.

Of importance to the Supreme Court was article 69 of the EPC, and the Protocol on the interpretation of article 69. Article 69 states:[151]

Article 69

(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Lord Neuberger, who delivered the unanimous judgment of the Court, considered articles 1 and 2 of the Protocol highly significant insofar as they described competing principles to weigh

[150] At [92].
[151] EPC, above n 99, at Art 69(1).

in interpreting article 69 in infringement claims. Those principles being "fair protection for the patent proprietor [and] a reasonable degree of legal certainty for third parties",[152] and additionally, to consider "any element which is equivalent to an element specified in the claims".[153] Lord Neuberger stated that in balancing the principles from the Protocol noted above, there are clearly conflicting interests that require a choice "between the appropriateness of giving an inventor a monopoly and the public interest in maximizing competition".[154] Clearly these latter two interests lie at the heart of why the patent system exists, and to what extent a party's interests shall extend.

Beginning with a discussion of the approach taken in *Actavis*, Lord Neuberger departed from Lord Diplock's identification of one issue in *Catnic* and stated that there are in fact two interpretation issues that should not be fused into one.[155] The Court identified the new test as:[156]

> (i) Does the variant infringe any of the claims as a matter of normal interpretation; and, if not,
>
> (ii) Does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?
>
> If the answer to either issue is "yes", there is an infringement; otherwise, there is not.

The first limb of the new test is a straight forward interpretation exercise, something that law professionals are already well versed with.[157] Lord Neuberger applied limb (i) to *Actavis*, noting that "according to normal principles of interpreting documents, the Actavis products do not infringe the Patent".[158] Lord Neuberger demonstrated his point with reference to *Improver*. He stated that in the same way as a "robber rod" cannot be a "helical metal spring", nor can pemetrexed diacid, pemetrexed ditromethamine or pemetrexed dipotassium be mistaken for pemetrexed disodium.[159]

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[152] Protocol on the Interpretation of Article 69 EPC, at Art 1 as cited in *Actavis* (SC), above n 1, at [31].
[153] Protocol on the Interpretation of Article 69 EPC, at Art 2 as cited in *Actavis* (SC), above n 1, at [31].
[154] At [32].
[155] At [55].
[156] At [54].
[157] At [58].
[158] At [58].
[159] At [58].

The second limb is more convoluted than the first, but this can be mitigated by using the three *Improver* questions which Lord Neuberger sought to amend in his analysis of *Actavis*.[160] Lord Neuberger was largely content with the first *Improver* question, merely identifying a drafting issue by Hoffman J.[161] He then moved onto the second *Improver* question, deeming it to insufficiently protect patentees.[162] The second question places an onus upon patentees that is difficult to satisfy as it requires the person skilled in the art or the notional addressee, to predict things that would not yet be in their breadth of knowledge at the time of the patent publication.[163]

Lord Neuberger was satisfied with the third *Improver* question, but was concerned about its potential to be misapplied, thus he provided four factors to consider when applying the third question.[164] He laid these factors out as:[165]

1) Although 'the language of the claim' is important, consideration of the third question certainly does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have.
2) The fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question.
3) When considering the third question, it is appropriate to ask whether the component at issue is an 'essential' part of the invention, but that is not the same thing as asking if it is an 'essential' part of the overall product or process of which the inventive concept is part.
4) When one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is … necessary to imbue the notional addressee with rather more information than he might have had at the priority date.

[160] At [59].
[161] *Actavis* (SC), above n 1, at [60].
[162] At [61].
[163] At [61].
[164] At [65].
[165] At [65].

Following these changes to the *Improver* questions, the Court set out its modified questions to address when answering limb (ii) of the infringement test. These questions are:[166]

i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?

ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

Applying the amended *Improver* questions, Lord Neuberger determined that Actavis's variant products infringed Eli Lilly's Patent.[167] The first question is satisfied because the Actavis products undoubtedly work in the same way as Eli Lilly's invention did.[168] The Supreme Court also ruled in favour of Eli Lilly on the second *Improver* question, stating that "when it comes to different versions of pemetrexed medicaments, it is clear that the use of a free acid, and of ditromethamine and dipotassium salts was in each case well established as at the priority date".[169] As for the third *Improver* question, Lord Neuberger was of the opinion that the Court of Appeal treated that question as a matter of normal interpretation which he found nonsensical as, in his opinion, it negated the need for the *Improver* questions in the first place if one of the questions was just a matter of plain interpretation.[170] Lord Neuberger noted that the Court of Appeal did not place sufficient emphasis on Article 2 of the Protocol, which requires consideration of "any element which is equivalent to an element specified in the claims".[171] The Supreme Court asserted that because Eli Lilly's specification referred to both anti-folates in the general sense, and pemetrexed disodium specifically, this indicates that Eli Lilly did not

[166] Actavis, above n 1, at [66].
[167] At [68].
[168] At [68].
[169] At [69].
[170] At [71].
[171] Protocol on the Interpretation of Article 69 EPC, at Art 2 as cited in *Actavis* (SC), above n 1, at [31].

intend for strict compliance of the wording of its claims.[172] Answering the three reformulated *Improver* questions affirmatively, the Court held that Actavis infringed claim 1 of Eli Lilly's Patent.[173]

Turning to the issue of indirect infringement of the Patent, the Supreme Court also upheld the Court of Appeal's ruling in favour of Eli Lilly.[174] Lord Neuberger noted that there is indirect infringement "if Actavis know, or it is obvious in the circumstances, that ultimate users will dilute [their products] in saline".[175]

4.4 The Significance of the UKSC decision in Actavis v Eli Lilly

Pith and marrow is back.[176] The UKSC decision in *Actavis* was groundbreaking, introducing a DoE into the UK patent system once more.[177] Lord Neuberger and the UKSC reformulated the three *Improver* questions which effectively introduced a DoE, creating the potential for erosion of the fundamental purpose of patent law. The Doctrine extends patent protection even when a variant product does not literally fit into the patent claims, but nonetheless operates in virtually the same way as the patented product to achieve a materially similar result.[178] When Lord Neuberger formally introduced a UK DoE in *Actavis*, he did so with a focus on acting in accordance with the requirements of the EPC and the Protocol, and also intending to align UK patent law with other European patent systems.[179]

The UKSC's judgment is a clear contribution to the extension of protection afforded to patentees, with variants more readily infringing patents through Equivalents via interpretation of the reformulated *Improver* questions,[180] even if the variant includes an inventive act.[181] This is significant because extensively broad patentee protection disincentivises innovation,[182]

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[172] *Actavis* (SC), above n 1, at [73].
[173] At [75].
[174] Actavis, above n 1, at [112].
[175] At [112].
[176] Jamieson, above n 84, at 152.
[177] Nicole Jadeja, Hannah Smith-Willis & Heidi Hurdle "Cast Back into the Sea of Uncertainty – A Doctrine of Equivalents in UK Law? The Supreme Court Ruling in *Actavis v Eli Lilly*" (2018) 13 JIPLP 565 at 568.
[178] Alexandra K Pechhold "The Evolution of the Doctrine of Equivalents in the United States, United Kingdom, and Germany" (2005) 87 PTOS 411 at 412.
[179] Kendrick, above n 130, at 51.
[180] Tanvi Shah, Jason Raeburn & Hiroshi Sheraton "Actavis v Eli Lilly: English Supreme Court Shakes Up Approach to Patent Infringement by Equivalents" (2017) 39 EIPR 778 at 782.
[181] Kendrick, above n 130, at 53.
[182] Kendrick, above n 130, at 45.

increases the procedural uncertainty of patent interpretation and leads to the formation of extensive monopolies to the demise of third party innovators who wish to enter a market that is riddled with uncertainty, and arguably leaves a gap between the required standards of interpretation for infringement and for validity.[183] Also, it is questionable whether the desire for judicial harmonization is substantively well-reasoned enough to impact matters of principle.[184] Bear in mind also that the fundamental reason for the UK patent system was to extinguish monopolies. Additionally, as per Lord Neuberger's judgment, variants that existed before *Actavis* was heard that were "designed around" already-patented inventions and were held to be non-infringing may actually infringe under the DoE due to the extensive patentee protection that Equivalents affords.[185] So, a decision that was "an intentional shift to greater consistency in the approach to patent construction, and other issues of patent law governed by the EPC",[186] has actually in hindsight created inherent uncertainty in the UK patent system that did not previously exist.[187] These concerns will be further explored in the following chapters.

[183] Alisa Carter "Mind the Actavis v Eli Lilly Gap Please!" (2017) Mind the Actavis Gap MBB at 1.
[184] Shah, Raeburn & Sheraton, above n 180, at 783.
[185] Shah, Raeburn & Sheraton, above n 180, at 782.
[186] Shah, Raeburn & Sheraton, above n 180, at 783.
[187] Jamieson, above n 84, at 153.

5.0 The Doctrine of Equivalents in Overseas Jurisdictions

5.1 Introduction

To further understand the DoE as it now applies in the UK following *Actavis*, it is helpful to analyse the Doctrine in other patent law systems, including in the US, Germany, Australia and Singapore. Understanding the policy rationales that justify having a DoE in other patent systems might provide insight into the impact of the Doctrine as a whole, and whether or not it is something that should be incorporated into New Zealand patent law.

5.2 The American Doctrine of Equivalents

The DoE is nothing new to the American patent system. The exact date of origin of the US Equivalents Doctrine is unknown,[188] however, the judicially formulated Doctrine has been modified through the common law, with *Winans v Denmead* being the first identifiable case to have used an Equivalents Doctrine (albeit without explicitly stating so).[189] *Graver Tank* was the first US case to describe the DoE.[190] The Federal Circuit in *Graver Tank* stated that "the essence of the Doctrine is that one may not practice a fraud on a patent".[191] This vague statement has been strengthened by the Federal Circuit to state that:[192]

> The Doctrine was established to make it impossible for "the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the literal scope of the claim, and hence outside the reach of law.

Therefore, it is evident that the US Equivalents Doctrine evolved from the perceived need for greater patentee protection, because it enables patentees to broaden their patent to encompass infringing technologies and inventions. Although, other than presenting the need for an Equivalents Doctrine from a "fairness-based" approach, *Graver Tank* actually offered no solid

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[188] Michael J Meurer & Craig Allen Nard "Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents" (2005) 93 GLJ 1947 at 1961.
[189] Darcy August Paul "The Judicial Doctrine of Equivalents" (2003) 17 HJLT 247 at 250.
[190] Paul, above n 189, at 256.
[191] *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 339 U.S. 605 (1950), at 1 as cited in Pechhold, above n 178, at 412.
[192] *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 339 U.S. 605, 607 (1950), at 3 as cited in Pechhold, above n 178, at 412.

principle for applying the Doctrine in that case.[193] Fairness for patentees entirely contradicts one of the fundamental reasons for the existence of the patent system; to provide notice to competing companies of what protected inventions exist in the market, and enabling competitors to sufficiently invent around those pre-existing technologies.[194] This was highlighted and mitigated to some degree in the case of *Festo Corp.*[195] following recognition that "the confines of patent law should not waver to the hindsight reflection of a patentee that argues for greater coverage during litigation".[196] In *Festo Corp.* Justice Kennedy identified that there is just as great a need to protect a patentee's proprietary interest as there is to protect certain outcomes to a degree for both competitors and the general public.[197] So, although fairness for a patentee is valued, courts in the US have recognised that fairness is just one element of the patent system, and that the issue of using a DoE in the US does not begin and end with fairness.

Consequently, the modern US DoE is regulated by the judiciary using two rules, but the Doctrine is still largely incoherent.[198] In the *Festo Corp.* litigation, the Supreme Court clarified the role of Prosecution History Estoppel in regulating the US approach to the Equivalents Doctrine.[199] The Court explained that although an Equivalents Doctrine can compromise public certainty, the existence of that uncertainty is necessary as "the price of ensuring the appropriate incentives for innovation".[200] Therefore, the Court developed a method of Prosecution History Estoppel that was neither too pro-patentee nor anti-patentee – the Court essentially formed a compromise to ameliorate the effect of the Doctrine.[201]

The introduction of the Doctrine did not come without reservations, with Justice Kennedy subsequently highlighting the unnecessary waste that the Doctrine is a contributor of.[202] For example, "the costs of the modern DoE to society…are immense (billions of dollars each year)"

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[193] Meurer & Nard, above n 188, at 1973.
[194] Pechhold, above n 178, at 413.
[195] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002), at 15 as cited in Pechhold, above n 178, at 414.
[196] Pechhold, above n 178, at 413-414.
[197] Meurer & Nard, above n 188, at 1982.
[198] Meurer & Nard, above n 188, at 1949.
[199] Pechhold, above n 178, at 415.
[200] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002), at 175 as cited in Meurer & Nard, above n 188, at 1982.
[201] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002), at 175 as cited in Meurer & Nard, above n 188, at 1982.
[202] Pechhold, above n 178, at 416.

and are still increasing,[203] with litigation becoming "increasingly common",[204] yet roughly 85% of patent cases that result in litigation in the US are found in favour of "alleged infringers", resulting in wasted litigation costs of up to $100 million each year.[205] "Presumably, many of these patent cases would be resolved at substantially less expense or would not be brought in the first place" if there was no existing DoE.[206] Three policy concerns have been identified in earlier US patent cases. First, that Equivalents Doctrines enable the judgment of fact finders to substitute the judgment of entities who are empowered to grant patents in the first place.[207] Second, concern that having a DoE negates the purpose for patents being made publicly available, in that patents can be amended to incorporate hindsight considerations, deteriorating public knowledge and the subsequent ability for the public to invent around but very closely to, a patented invention.[208] Third, the DoE leads to monopolistic practices that threaten competition.[209] The Supreme Court in *Festo* also pointed to economic setbacks that the Doctrine would create, including uncertain patent scope, discouragement of competition, and needless litigation at high costs.[210] The Supreme Court determined that the DoE inquiry is initiated with the presumption that "a narrowing amendment is a 'general disclaimer of the territory between the original claim and the amended claim'".[211] This presumption acts as a rebuttable gatekeeper that allows the DoE to be used, however, if the presumption is not rebutted then a patentee cannot invoke the DoE.[212] The presumption can be rebutted if the patentee can show that:[213]

> At the time the application was filed, a person having ordinary skill in the art would have literally claimed the equivalent but did not because [1] [t]he equivalent may have been unforeseeable at the time of the application; [2] the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or [3] … some other reason

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[203] Joshua D Sarnoff "Abolishing the Doctrine of Equivalents and Claiming the Future After Festo" (2004) 19 BTLJ 1157 at 1196.
[204] Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1353 (Fed. Cir. 2000), n 162 as cited in Sarnoff, above n 203, at 1197.
[205] Sarnoff, above n 203, at 1199.
[206] Sarnoff, above n 203, at 1199.
[207] Meurer & Nard, above n 188, at 1953.
[208] Meurer & Nard, above n 188, at 1953-1954.
[209] Meurer & Nard, above n 188, at 1954.
[210] Pechhold, above n 178, at 416.
[211] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002), at 175 as cited in Meurer & Nard, above n 188, at 1982.
[212] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002), at 175 as cited in Meurer & Nard, above n 188, at 1982.
[213] Meurer & Nard, above n 188, at 1982-1983.

suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

Some scholars recognise that patent law now operates in a fluid society and rather than creating limited, strict rules, patent systems across various jurisdictions aim to create a coherent and consistent approach to patent interpretation.[214] It is questionable though whether achieving the desired coherency is best done using Equivalents. In saying that, given the DoE is well-accepted and is frequently altered to meet societal standards, patent systems have become "further entrenched in this meticulous doctrine".[215] This suggests that several patent law jurisdictions have become so familiar with the DoE that maintaining the Doctrine and constantly amending it to align with the justifications for patent law is far easier than eliminating the Doctrine altogether.

Although, having this Doctrine contributes to the growing amount of patent litigation in the US at extortionate costs which seem to further undermine the need for having a DoE at all.[216] These costs are not relative to the amount of money at issue either – litigation costs are high, and the technology at issue is often not worth enough to justify expensive litigation.[217]

The fact that so many exceptions apply to the US patent system to enable a workable DoE, yet there is still ample instability in relation to the application of the Doctrine, suggests that the DoE is an undesirable feature of the patent system. The US DoE still contains more imperfections than having the Doctrine is worth. So, how far will the DoE develop and expand before the justifications for the why patent system become lost in translation?

5.3 The German Doctrine of Equivalents

Well-accepted in Germany[218] for "innovative contributions to the art", the DoE serves to extend the scope of patent protection.[219] Compared with the UK approach which transpired to remedy the issue of monopolies in the UK, there is a greater chance of wide patent protection being

[214] Pechhold, above n 178, at 435.
[215] Pechhold, above n 178, at 436.
[216] Pechhold, above n 178, at 436.
[217] Pechhold, above n 178, at 436.
[218] Philipp Widera "Convergence between Germany and UK" (2017) MIP 1 at 1.
[219] Pechhold, above n 178, at 421.

awarded to prospective patentees in Germany, which clearly favours patentees more than the UK approach does.[220]

Where the UK approach to the DoE involves considering the three *Improver* questions as reformulated by *Actavis*, the German approach similarly involves considering the *Schneidmesser* Questions.[221] These questions, all of which are to be answered in the affirmative in order to invoke the Doctrine are:[222]

1. Does the modified embodiment solve the problem underlying with means that have objectively the same technical effect/advantage?
2. Was the person skilled in the art, using his specialist knowledge, able to find the variant at the priority date as having the same effect?
3. Are the considerations which the skilled person takes into account for the variant in light of the meaning of the invention close enough to the considerations taken into account for the literal solution protected by the claims, such that the skilled person will consider the variant as a solution which is equal/equivalent to the literal one?

The *Schneidmesser* approach also importantly involves a fourth step; the "*Formstein* objection".[223] This objection is invoked when a patent that is extended to cover an equivalent variant following three affirmative answers to the questions above is consequentially extended to cover products or processes in the prior art, therefore lacking the novelty requirement for patent protection.[224] The *Formstein* defense "identifies the key policy concerns surrounding expansion of the scope of patent claims through equivalents".[225] When applied, *Formstein* finds that a patent cannot be expanded to include equivalents that are not novel or that form part of the prior art and are therefore unpatentable.[226] This *Formstein* objection demonstrates that the German approach to the DoE consistently works to maintain the rationales for the patent system.

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[220] Pechhold, above n 178, at 421.
[221] Paul England "A German Solution to Address UK Patent Scope" (2019) MIP 1 at 4.
[222] England, above n 221, at 4.
[223] England, above n 221, at 4.
[224] England, above n 221, at 4.
[225] Katherine E. White "Festo: A Case Contravening the Convergence of Doctrine of Equivalents Jurisprudence in Germany, the United Kingdom, and the United States" (2001-2002) 8 MTTLR 1 at 24.
[226] Valentyna Chekanska "The Doctrine of Equivalents in Patent Law: The Impact of Actavis v Eli Lilly" (2019) 18 HLJ 68, at 83-84.

5.4 The Australian Approach

The Australian approach to patent interpretation is similar to the stance taken in New Zealand. Australian courts exhibit varying responses to the relevance and applicability of the *Improver* questions,[227] as do New Zealand courts.[228] Be that as it may, it is well accepted in Australia that the purposive construction coined in *Catnic* and endorsed by *Improver* and *Kirin-Amgen*, is directly relevant in Australia, having been frequently reaffirmed in Australian courts.[229] At present, the Australian approach to patent interpretation can be holistically described as:[230]

> A claim is to be construed from the perspective of a person skilled in the relevant art as to how such a person, who is neither particularly imaginative nor particularly inventive (or innovative), would have understood the patentee to be using the words of the claim in the context in which they appear… a "purposive rather than a purely literal construction" is to be given.

The DoE does not currently apply in Australia. Since *Actavis* was heard in the UK Supreme Court, some literature has discussed the potential for an Australian DoE. The Australian approach to *Actavis* may have no notable effect on the way in which Australian patent law operates and is enforced in the courts.[231] Although Lord Neuberger thought it necessary to specify the two questions central to the new patent law approach and to reformulate the *Improver* questions to enable the Protocol to be sufficiently considered in UK law, some argue that "this may be a distinction without a difference".[232] In other words, the Australian position is contextually fluid enough.[233] In saying that, the Australian approach provides unpredictable outcomes for inventors who find themselves in potential breach of a patent because of their variant.[234] In that sense, *Actavis* may provide a workable adaptation to Australian patent law in the form of the amended *Improver* questions, making adaptation of *Actavis* into Australian patent law a prospective course of action.[235] Irrespective of whether or not Australian courts will enforce the *Actavis* DoE, they will likely exhibit caution when considering the case due to

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[227] James Lawrence "Patent Infringement Post-*Actavis v Eli Lilly*: the Treatment of Equivalents in the United Kingdom and in Australia" (2018) 112 IPF:JIIPSANZ 8 at 11.
[228] See discussion in chapter 3.4 on *Improver* in New Zealand.
[229] Lawrence, above 227, at 11.
[230] *ESCO Corporation v Ronneby Road Pty Ltd* [2018] FCAFC 46 at [144], n 29 as cited in Lawrence, above 227, at 11.
[231] Lawrence, above 227, at 15.
[232] Lawrence, above 227, at 15.
[233] Lawrence, above 227, at 15.
[234] Lawrence, above 227, at 15.
[235] Lawrence, above 227, at 15.

the imbalance of patent scope between seeking initial patent protection at the novelty stage and when seeking to protect a patent from potential infringers.[236]

5.5 Singapore's Court of Appeal Rejects Actavis v Eli Lilly

In 2018, the year following the UKSC's adoption of a DoE, Singapore's Court of Appeal rejected the application of *Actavis* in Singapore.[237] In doing so however, the Court of Appeal noted that the consideration of a Singapore DoE is open for determination by Singapore's legislators.[238]

One commentator has provided a wealth of arguments rationalizing the Court of Appeal's decision not to adopt a DoE, the most prevailing justification being to uphold the consistently high standards that parties in unilateral agreements are held to in other disciplines of the law in Singapore.[239] The DoE would significantly broaden protection for patentees and would therefore be irreconcilable with holding patentees to these high standards without appropriate justification.[240]

This decision by the Court of Appeal appears to logically follow Singapore's approval of *Kirin-Amgen*, a case which expressly rejected a UK DoE, despite the fact that Singapore courts have never explicitly considered whether or not a DoE applies in Singapore.[241] In saying that, arguments resembling Equivalents have been discreetly raised in Singapore cases and have been rejected.[242]

The first case in Singapore to consider *Actavis* to the extent of ruling on its applicability was *Lee Tat Cheng v Maka GPS Technologies*.[243] In its decision not to adopt a Singapore DoE, the Court of Appeal offered three reasons.[244] First, Singapore is not a member of the EPC, so the Convention and the Protocol are not applicable in Singapore, but were a primary reason for the

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[236] Lawrence, above 227, at 15.
[237] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [54], n 14 as cited in Ching Yu Jin Bryan "Retaining the Catnic/Improver Approach in Patent Law" (2018) 30 SALJ 871 at [3].
[238] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [53], n 16 as cited in Bryan, above n 237, at [3].
[239] Bryan, above n 237, at [6].
[240] Bryan, above n 237, at [6].
[241] Bryan, above n 237, at [3].
[242] *Bean Innovations Pte Ltd v Flexon (Pte) Ltd* [2001] 2 SLR(R) 116. Bryan, above n 237, at [29].
[243] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856.
[244] Bryan, above n 237, at [32].

decision by the UKSC to adopt a DoE.[245] Second, the Singapore patent system values fairness, thus the Court of Appeal held that patentees should be held to the wording that they have chosen and have publicly registered.[246] Thirdly, certainty is a strong value of the patent system and the Court of Appeal was of the opinion that the purposive approach to patent interpretation offers more certainty than the DoE does.[247]

Following *Lee Tat Cheng*, a commentator has stated that "the DoE should only be adopted if an assessment of these 'competing interests' (*viz*, fair protection to the patentee, innovation and certainty) leads to the conclusion that the DoE results in a more optimal balance as compared to the purposive approach".[248] The same commentator also analysed some of these competing interests, alongside the frequently used argument that having a DoE will lead to greater harmonisation between patent regimes internationally.[249] The necessity for the argument for greater harmonisation is contentious though, because there is no general consensus for a movement towards harmonisation internationally and is in reality still an obvious upholding of the purposive approach to interpretation.[250]

In Singapore the need for a fair patent system is notable, however "fairness to the patentee does not justify adopting the DoE when the unfairness is said to result from a decision made during patent application or imprecise claims".[251] Further, as one of the justifications for the existence of patent regimes, incentive to innovate is often used to justify the need for a DoE. Although, there is no evidence to suggest an increased incentive to innovate following the introduction of a DoE. On the contrary, the presence of a DoE might result in decreased innovation as it limits competitors from contributing to the market by building upon patented inventions.[252] Moreover, it readily follows that patentees will also be less incentivized to improve their own technologies if the prospect of competition is impeded by an Equivalents Doctrine.[253]

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[245] Bryan, above n 237, at [33].
[246] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [52], n 100 as cited in Bryan, above n 237, at [34].
[247] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [53], n 100 as cited in Bryan, above n 237, at [34].
[248] Bryan, above n 237, at [48].
[249] Bryan, above n 237, at [51].
[250] Bryan, above n 237, at [51].
[251] Bryan, above n 237, at [61].
[252] Bryan, above n 237, at [63].
[253] Merges and Nelson, above n 24, at 908.

The Court of Appeal also reasoned that the DoE will undermine certainty by allowing the potential for patent scope to expand beyond the words of the claims into a realm of unpredictability.[254] Additionally, the Doctrine itself exists in an unstable manner; a multitude of limitations work to circumvent the potential harms presented by a DoE but such limitations are inconsistent across patent regimes.[255] Arguably, the justifications often presented in favour of the DoE inadequately rationalize the existence of the Doctrine,[256] thus Singaporean courts have declined to adopt a DoE, leaving the matter open to Parliament.[257]

[254] Bryan, above n 237, at [67].
[255] Bryan, above n 237, at [68].
[256] Bryan, above n 237, at [76].
[257] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [53], n 95 as cited in Bryan, above n 237, at [31].

6.0 Following *Actavis* – Should New Zealand Adopt a Doctrine of Equivalents?

6.1 The Current Patent Law in New Zealand

New Zealand patent law is, as aforementioned, primarily governed by the Patents Act 2013. Most importantly, the owner of a patent has "exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention".[258] Section 14 of the Act sets out patentability requirements, stating that:

> An invention is a patentable invention if the invention, so far as claimed in a claim, –
> (e) Is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
> (f) When compared with the prior art base –
> (iii) Is novel; and
> (iv) Involves an inventive step; and
> (g) Is useful; and
> (h) Is not excluded from being a patentable invention under section 15 or 16.

Sections 15 and 16 sets out the exemptions from patentability in New Zealand as follows:

> **15 Inventions contrary to public order or morality not patentable inventions**
> (1) An invention is not a patentable invention if the commercial exploitation of the invention, so far as claimed in a claim, is contrary to –
> (a) Public order (which in this section has the same meaning as the term *ordre public* as used in Article 27.2 of the TRIPs agreement); or
> (b) Morality.
>
> **16 Other exclusions**
> (1) Human beings, and biological processes for their generation, are not patentable inventions.
> (2) An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.
> (3) An invention of a method of diagnosis practised on human beings is not a patentable invention.

[258] Patents Act, s 18(1).

(4) A plant variety is not a patentable invention.

(5) …

New Zealand courts are yet to address the issue of a New Zealand DoE, but current patent infringement interpretation in New Zealand turns upon the consideration of three historic UK cases; those being *Catnic*, *Improver*, and *Kirin-Amgen*. Without a DoE in New Zealand, "a patentee can only allege infringement of that which a patent claims".[259] To determine precisely what a patent claims in New Zealand, the patent must be interpreted according to the rules on purposive construction from *Catnic*.[260] In *Catnic,* Lord Diplock stipulated that the test for patent interpretation is:[261]

> Whether a person with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.

The relevance of *Actavis* to the New Zealand patent system is in contention. Given the New Zealand position on the application of the original *Improver* questions is as yet not fundamentally clear, it is equally unclear whether New Zealand will adopt the *Actavis* reasoning, including a future DoE in any future litigation. Although, it is arguably inevitable that New Zealand will eventually adopt its own DoE as the courts take account of international developments.[262]

6.2 Based on the Principles of Patent Law, should New Zealand Adopt a Doctrine of Equivalents?

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[259] *Rodi & Weinberger AG v Henry Showell Ltd* [1969] RPC 367 (HL) per Lord Morris, at 18 as cited in Frankel & Lai, above n 8, at 247-248.
[260] Frankel & Lai, above n 8, at 248.
[261] *Catnic*, above n 2, at [243].
[262] Patents Act, s 3(e).

6.2.1 The EPC and the Protocol

In *Actavis*, Lord Neuberger and the House of Lords placed considerable emphasis on the application of the EPC, particularly Article 69 of the EPC and Article 2 of the Protocol on interpretation of Article 69.[263] The UKSC was undeniably attempting to align the UK patent system with other European patent systems that utilise a DoE in infringement interpretation cases. In saying that, the desire to align the UK with other European patent jurisdictions did not develop from an inadequacy of the *Catnic* purposive approach coupled by the original *Improver* questions, but actually derived from the UK's insufficient consideration of equivalents as required under Article 2 of the Protocol of the EPC.[264] Given New Zealand is not a party to the EPC, the relevance to New Zealand of the UKSC's reasoning in *Actavis* becomes unsettled.

The Preamble of the EPC states that the EPC exists to achieve consensus across EPC signatories "by the establishment of certain standard rules governing patents".[265] Arguably, the best method for achieving this consensus is to incorporate the EPC and its articles and interpretive aids into current patent systems.[266] However, the need to do this in New Zealand is arguably artificial. Although judicial harmonisation across different patent jurisdictions is desirable, New Zealand does not have international EPC obligations to comply with. That is not to say that the question of a DoE in New Zealand is to be ruled out entirely, but instead demonstrates that there is, as is clear from the UKSC's reasoning in *Actavis*, no need for New Zealand patent law to immediately incorporate the judgment from *Actavis*. New Zealand patent law evidently shows that international patent developments are a relevant consideration.[267]

6.2.2 Inherent Uncertainty Following Incorporation of the Doctrine of Equivalents and its Impact on Innovation

Turning now to consider whether New Zealand should adopt, the DoE adds considerable uncertainty to an intellectual property system that requires high levels of certainty in order to function.[268] In allowing patent claims to expand beyond the original patent scope, a patentee is granted a stronger exclusive property right giving them a greater monopoly to the detriment of

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[263] Koedyk, above n 90, at 16.
[264] Koedyk, above n 90, at 16.
[265] Jamieson, above n 84, at 151.
[266] Jamieson, above n 84, at 151.
[267] Patents Act, s 3(e).
[268] Cianfrani, above n 129, at [29].

other inventors.[269] Some academics argue that this broadening of the scope of patents through Equivalents is a "serious drawback given that patents are very often justified on the grounds that they promote innovation".[270] By widening patent scope to heighten protection to patentees, the risk of improvements upon already-patented technology ending up in infringement litigation increases.[271] This has the effect of reducing inventive incentives; conversely, when the scope of a patent more accurately reflects the invention, third party inventors know what the scope is and can more confidently innovate outside that scope, investing in research and development of technologies.[272]

The DoE aims to form a compromise between the rationales for patent law; on one hand ensuring that patents provide sufficient notice to the public of the specific bounds of a patent, and on the other hand protecting the exclusive rights afforded to a patentee through the registration of a patent.[273] The patent system serves to promote two equally important purposes,[274] purposes which are arguably curtailed by Equivalents Doctrines. These purposes are:[275]

> To enable the public to make and use the invention once the statutory period has expired and to make use of the disclosure to develop improvements even before the patent expires. Second, the disclosure serves to provide notice to the public of the boundaries of the patent grant, thereby enabling parties to avoid infringement and to "design around" the patent. In this way, further advances in the field of the disclosed invention can be made even before the patent expires.

When a patent system employs a DoE, these core principles of patent law will be undermined because it is no longer possible to know the full bounds of patent protection to sufficiently innovate around the patent. In that sense, the DoE can act as a natural inhibitor to inventors who are thwarted by unpredictable claim construction,[276] potential litigation, astronomical litigation costs, and the growing uncertainty of litigation outcomes.[277] Society will

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[269] Cianfrani, above n 129, at [36].
[270] Kendrick, above n 130, at 63.
[271] Merges and Nelson, above n 24, at 916.
[272] Merges and Nelson, above n 24, at 916.
[273] Cianfrani, above n 129, at [29].
[274] Cianfrani, above n 129, at [4].
[275] Cianfrani, above n 129, at [4].
[276] Kendrick, above n 130, at 64.
[277] Cianfrani, above n 129, at [47].

consequentially lose out as innovators are less inclined to invent new technologies in the face of this growing uncertainty,[278] and remember that the Statute of Monopolies was first introduced to increase innovation and prevent detrimental monopolies. These negative impacts of the DoE have been recognised in the US where the DoE has been amended with "exception added to exception, and presumptions rebutted by still newer presumptions".[279] Each exception is created to fix the wide scope of the DoE, but each exception equally adds to the growing uncertainty that the DoE creates. As a result, patent applicants rarely amend their claims, but do however "file more claims and more specific claims and opt for less precise functional claims in an attempt to include equivalents".[280] So, in the US innovators are developing technologies and are filing more claims to err on the side of caution in the hopes that their product will be well protected, defeating the purpose of the patent system which is to prevent monopolistic markets.

Additionally, in *Actavis* Lord Neuberger and the House of Lords held that new technologies involving an inventive step may still infringe a patent using the DoE.[281] This is in complete contrast to Lord Neuberger's assertion through the reformulated *Improver* questions that the UK's DoE is engaged when a variant technology is "immaterial" to the patented technology.[282] As such, "Lord Neuberger's stance on inventive equivalents introduces a confusing element into the doctrine that may hinder innovation by weakening the position of competitors".[283]

The social costs of reducing incentives to innovate are significant and particularly detrimental in the healthcare sector. This could adversely affect the amount of research and development of pharmaceuticals and treatment regimens in New Zealand.[284] This also has an adverse impact on the pharmaceutical sector which involves a significant amount of "incremental innovation", or simply, research and innovation building on pharmaceuticals already in existence.[285] These concerns can arguably be avoided in New Zealand patent law if New Zealand rejects the application of *Actavis* and maintains distance from adopting any form of Equivalents Doctrine.

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[278] Cianfrani, above n 129, at [47].
[279] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* ("Festo III"), 344 F.3d 1359, 1376 (Fed. Cir. 2003), n 66 as cited in Pechhold, above n 178, at 420.
[280] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* ("Festo III"), 344 F.3d 1359, 1375 (Fed. Cir. 2003), n 68 as cited in Pechhold, above n 178, at 420.
[281] Kendrick, above n 130, at 65.
[282] Kendrick, above n 130, at 65.
[283] Kendrick, above n 130, at 66.
[284] Kendrick, above n 130, at 66.
[285] Kendrick, above n 130, at 64.

Such rejection of *Actavis* and of a DoE will ensure that inventors know what constitutes the prior art and can innovate around that.[286]

6.2.3 The Need for a Fair Patent System

Turning now to arguments often presented in favour of a DoE, the Doctrine was first introduced to provide fair protection for patentees following concerns that patent law inadequately protected patentees.[287] As the majority in *Winans v Denmead* held, there is concern for "the fair treatment of the inventor and punishing the putative unscrupulous behaviour of the infringer".[288] In saying that, patentee protection should not be so strong that inventors are less inclined to innovate, because nor is this fair. Arguably, a fair patent system absent of a DoE will evenly balance the innovative rights of patentees and third-party competitors in the public.[289] This balance is disrupted in a patent system where notice is removed due to the ambiguity that a DoE creates.[290] This ambiguity arises in the form of there being "no objective way of determining when something is similar enough to an existing invention to warrant expanded protection, and there is no way of determining exactly how far to extend a patentee's rights".[291]

There is no need to protect patentees to an extent that the public is prevented from knowing the exact boundaries of a patent, because the rights of patentees do not exceed the rights of the public in having sufficient knowledge of existing property protection.[292] In appropriately balancing the two sets of rights, competition will continue to thrive, with competitors being more certain of the legal limitations of patented inventions.[293] For that reason, the Doctrine should not be introduced into New Zealand patent law.

The existence of an Equivalents Doctrine arguably incentivizes patentees to claim narrowly during the patent registration process in order to satisfy the novelty requirement for patent registration, and then later argue for a wider patent scope at the infringement stage by using

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[286] Sturicz, above n 132, at 405.
[287] Sturicz, above n 132, at 394.
[288] Winans v. Denmead, 56 U.S. 329, 342-43 (1853), n 60 as cited in Sturicz, above n 132, at 397.
[289] Sturicz, above n 132, at 403.
[290] Sturicz, above n 132, at 404.
[291] Sturicz, above n 132, at 404.
[292] *Festo II,* 535 U.S. 722, 731-32 (2002), n 27 as cited in Aaron P Bowling "Just About Equivalent: A Comparative Analysis of the Doctrines of Equivalents in the United States and International Jurisdictions Shows that the Varying Doctrines are Strikingly Similar" (2013) 41 AIPLA QJ 553at 560.
[293] *Festo I*, 234 F.3d at 597 (Lourie, J., concurring), n 31 as cited in Bowling, above n 292, at 560.

the DoE.[294] This allows patentees to claim a patent scope they desired from the outset, but knew they might not achieve due to it breaching the requirement of novelty as compared to the prior art. It equally allows patentees to retroactively rectify their own drafting mistakes to the detriment of new inventors in the market who will be held to be infringing the patent by Equivalents.[295] This is a completely unfair system of property rights and wholly undermines the rationales of having a patent system at all; ie the need to prevent injurious monopolies that result in one company being able to innovate, while others cannot. Whilst it is socially desirable for inventors to be incentivized to continue investing time, money and energy into inventing new technologies, this should not be achieved to the detriment of society benefitting from an abundance of available technologies. In allowing patentees to hold a greater monopoly right than they are entitled, one of the fundamental purposes in s 3(a)(i) of the Patents Act is undermined due to the failure to appropriately balance rights. In the UK, patent law supposedly favours the public interest, with the patent system being the only exception to monopolies in the UK,[296] although since the decision in *Actavis* this is hardly the case. A DoE unequivocally favours patentees, and this is something that New Zealand should be wary of adopting, bearing in mind the desirability to prevent the formation of monopolies.

The rights of patentees and of third-party innovators are rights that need to be finely balanced, which is no easy feat.[297] There are costs and benefits to patentees and society, whichever route taken.[298] Although it is argued that balancing these costs and benefits is only made more difficult using a DoE, an interpretive approach that so clearly favours the interests of patentees. Ultimately, the need to prevent detrimental monopolies arguably outweighs any benefits of having the DoE.

6.2.4 Interpretation of Construction vs Infringement and Claim Inelasticity and the Prior Art

Since the UKSC decided *Actavis* it has been confirmed that claim construction for the purposes of determining validity, continues to be purposive construction,[299] whilst the DoE only applies to infringement claims. The act of purposively constructing patent claims in question of validity

[294] Kendrick, above n 130, at 58.
[295] Sturicz, above n 132, at 394.
[296] Ray D Weston Jr *A Comparative Analysis of the Doctrine of Equivalents: Can European Approaches Solve an American Dilemma?*, 39 IDEA 35, 49 (1998), n 34 as cited in Bowling, above n 292, at 561.
[297] Cianfrani, above n 129, at [29].
[298] Cianfrani, above n 129, at [44]-[50].
[299] Richard Miller QC, Guy Burkill QC, His Honour Judge Birss QC & Douglas Campbell *Terrell on the Law of Patents* (19th ed, Sweet & Maxwell UK, UK, 2021) at 9-[34].

is to be done from the perspective of "the person skilled in the art and that exercise involve[s] interpreting the words of the claim in context".[300] The context must therefore be informed by the purpose for having a patent, which is to describe and protect an invention.[301] Traditionally, the method of claim construction has been the same whether it is validity or infringement in question.[302] The fundamental justification for this consistency was the notion that a patentee should be tied to a firm meaning of their claims rather than allowing malleable claims that can be narrowed in order to achieve patent validity and expanded at the infringement stage to encompass variant technologies.[303]

Now following *Actavis* though, infringement is no longer assessed using principles of construction.[304] If a variant does not infringe a patent on a literal basis then the *Improver* questions will be engaged, and answering the reformulated *Improver* questions is not a matter of construction.[305] Consequentially, patent protection could be expanded beyond the claims of a patent, allowing a patentee to claim a wider scope of protection than they were granted at the validity stage.[306] In a sense, this creates patent protection that can be molded enough that it is condensed or expanded depending on the proceeding in question; ie whether it is a validity or infringement proceeding, providing patentees optimal flexibility in patent protection.[307]

Following the substantial alterations made to the second *Improver* question, the person with knowledge in the prior art is bestowed more knowledge than they were in pre-*Actavis* times.[308] Therefore, a patent's scope is likely to expand overtime as the person skilled in the prior art is attributed with ever-increasing knowledge, with the result being each variant that enters the market is more obvious than the last.[309] This is problematic because "it is conceivable that a prior art embodiment which was not obvious at the priority date later becomes obvious and therefore constitutes an infringement pursuant to the DoE".[310] This fundamentally weakens the

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[300] *Generics (UK) Ltd v Yeda Research and Development Co Ltd* [2017] EWHC 2629 (Pat) at [138] as cited in Miller, Burkill & Birss, above n 299, at 9-[35].
[301] *Generics (UK) Ltd v Yeda Research and Development Co Ltd* [2017] EWHC 2629 (Pat) at [138] as cited in Miller, Burkill & Birss, above n 299, at 9-[35].
[302] Miller, Burkill & Birss, above n 299, at 9-[43].
[303] Miller, Burkill & Birss, above n 299, at 9-[43].
[304] Jamieson, above n 84, at 152.
[305] Jamieson, above n 84, at 152.
[306] Jamieson, above n 84, at 152.
[307] Miller, Burkill & Birss, above n 299, at 9-[43].
[308] Jamieson, above n 84, at 153.
[309] Jamieson, above n 84, at 153.
[310] Jamieson, above n 84, at 153.

purpose for the patent system; namely to prevent injurious monopolies.[311] If a patent can be expanded to encompass the prior art via infringement in post-*Actavis* UK patent law then that patent is not "truly inventive" and theoretically does not meet the legal requirements for patentability.[312] This is not a risk that New Zealand should take by adopting *Actavis* into its patent system.

6.2.5 Why the Harmonisation Argument Falls Short of Adequate Justification

The desire for harmonisation across patent regimes internationally is well-recognised due to the wealth of possible advantages that harmonisation could bring.[313] Arguably the most prevailing advantage is the increase in certainty that will follow this harmonisation.[314] Once a patentee has secured patent registration, in a harmonised patent system, infringement should be assessed the same across different countries, achieving the same results.[315]

In saying that, harmonisation is a "weak" justification for introducing a DoE,[316] it lacks any "substantive" reasoning,[317] and is also arguably defective considering different jurisdictions already adopt their own individual national approaches to patent protection and to the DoE. Even in the context of the EPC and the Protocol, which "was intended to achieve harmonis[ation in] the treatment of patents across its signatories",[318] it is questionable whether harmonisation will be substantively achieved due to varying patent law regimes and DoE approaches across EPC states. Any judicial attempts to create this desired harmonisation will largely fall short of the intended goal, which is to create entirely harmonious regimes.[319] In that sense, even if harmonisation is achieved on a surface level through the adoption of a DoE in all patent regimes, including in New Zealand, the likelihood of there being harmony between all patent regimes is remote due to the difference in each regime's domestic and international patent obligations. Moreover, as mentioned above in chapter 6.2.5, New Zealand is not a signatory of the EPC; even if the harmonisation argument adequately justified adopting a DoE, this hardly applies to New Zealand, a state absent of any obligations to the EPC. To achieve

[311] Jamieson, above n 84, at 153.
[312] Jamieson, above n 84, at 153.
[313] Walsh, above n 332, at 410.
[314] Walsh, above n 332, at 410.
[315] Walsh, above n 332, at 410.
[316] Bryan, above n 237, at [51].
[317] Bryan, above n 237, at [53].
[318] Jamieson, above n 84, at 154.
[319] Kendrick, above n 130, at 57.

optimal harmonisation within the international patent system, this must be attempted by some supreme authority,[320] and for that reason, harmonisation through the DoE following *Actavis* fails to justify the need for Equivalents in New Zealand.

6.2.6 Treatment of the Doctrine of Equivalents and Actavis in Other Jurisdictions

Several common law jurisdictions use some form of Equivalents Doctrine in their patent regimes, including the United States, Germany and France.[321] In saying that, several other jurisdictions are wary of incorporating a DoE, including Australia, whilst Singapore has outright rejected the application of *Actavis* and the DoE altogether, unless incorporated through legislation.

Despite the fact that the US has utilised a DoE for some time now, the Doctrine has created significant problems in the US that have required further judicial intervention to delineate its scope.[322] Such interventions include Prosecution History Estoppel as discussed above in chapter 5.2. The need to introduce PHE into US patent interpretation as a gatekeeper for use of Equivalents was emphasized in *Festo*, which stated that PHE is used to ensure that the DoE is used only for its intended purpose.[323] This seems to suggest that Equivalents often exceeds its intended purpose, offering more protection than it should, which corresponds to complex litigation and inherent uncertainty in the patent system.

Furthermore, in *Lee Tat Cheng*, Singapore's Court of Appeal outright rejected the application of *Actavis* in Singapore's patent system for a number of reasons.[324] These reasons include the fact that the EPC and the Protocol do not apply in Singapore;[325] that the desire for fairness for patentees is a weak reason for adopting a DoE;[326] and because of the increased uncertainty that having Equivalents creates.[327]

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[320] Kendrick, above n 130, at 62.
[321] As discussed above in chapter 5.
[322] Bryan, above n 237, at [42].
[323] *Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co* 535 US 722 at 734 (2002), n 128 as cited in Bryan, above n 237, at [42].
[324] Bryan, above n 237, at [29].
[325] Bryan, above n 237, at [33].
[326] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [52], n 100 as cited in Bryan, above n 237, at [34].
[327] *Lee Tat Cheng v Maka GPS Technologies Pte Ltd* [2018] 1 SLR 856 at [53], n 102 as cited in Bryan, above n 237, at [34].

Slightly closer to home, Australia too is suspicious of adopting a DoE because of the broad scope of protection that the Doctrine affords to patentees, creating a divergence in the scope of a patent when it is first registered by a patentee and when a new scope is later argued at the infringing stage.[328] Ample literature exists which discusses the DoE in various patent systems, the majority of which focuses on the inadequacies of the DoE, and potential ways to remedy the Doctrine's application. Ref such material In particular, the US appears to be moving away from any form of Equivalents through the implementation of Doctrine-limiting rules.[329] It naturally follows that if there is a need for a multitude of means to limit the DoE, then this suggests Equivalents inadequately resolves the issues it was introduced to address. Adding rules upon rules in an attempt to rectify the problems created by the DoE is inefficient, this is a problem that the New Zealand patent system should avoid in order to protect the fundamental justifications for having a patent system. Those justifications are the need to prevent inventors from holding large monopoly rights, to the detriment of other innovators who will struggle to invent around a monopoly, and to the detriment of society who will notice an increase in the price of technologies owned by companies that hold strong monopoly rights.

In this section I have presented principle-based objections, as well as incorporating consequentialist arguments to support my critique of the DoE. Overall, for the reasons stated above, I am of the opinion that it would be more harmful than helpful if the New Zealand patent system adopted a DoE.

6.3 The Impact of a New Zealand Doctrine of Equivalents on Patenting Pharmaceuticals

The DoE applies across all industries and all patentable inventions; however, this dissertation focuses particularly on the application of the DoE to the pharmaceutical industry. The pharmaceutical industry is a field with high stakes as every individual is a stakeholder in the healthcare realm; everyone interacts with the healthcare system at some point in their life. Therefore, there is a significant public interest in ensuring that pharmaceuticals and therapies are readily available and affordable to the general public. Pharmaceutical companies will arguably be disincentivised to innovate in the presence of a DoE due to the growing uncertainty that a DoE brings. This threatens to reduce rates of healthy competition.

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[328] Lawrence, above 227, at 215.
[329] Eugene Lim, "Opening the 'Pandora's Box' of Patent Claim Construction" (2016) 16 Asper Rev Int'l Bus & Trade L 155 at 169, n 157 as cited in Bryan, above n 237, at [52].

The healthcare sector substantially relies upon incremental innovation,[330] ie innovation that results in "follow on drugs" improving upon pre-existing drugs.[331] Consequently, the DoE will arguably inhibit the development of follow on drugs. There are an abundance of reasons demonstrating why incremental innovation is essential to pharmaceutical sector specifically. There are also a number of negative effects that will result from disallowing this incremental innovation, including effects that will arguably negatively impact affordable healthcare in New Zealand. Incremental innovation is valuable because it enables patients to undergo therapies most suitable to them. This in turn ensures that patients will maintain their treatment regimen, and pharmaceutical companies can also improve upon existing drugs to ensure they are up to modern standards.[332] Finally, competition increases, decreasing drug prices.[333] These benefits are likely to diminish in a patent regime that adopts *Actavis* and a DoE.[334]

The development of pharmaceuticals is an "inherently dynamic process" where "one innovation builds on another and improvements draw from a long history of earlier technological advances".[335] In fact, evidence shows that the bulk of all medical and pharmaceutical advancements are occurring through incremental innovation.[336] The DoE has an adverse effect on the ability of inventors to incrementally innovate.[337] Incremental innovation serves a beneficial purpose "to both patients and society, for both health and cost-saving reasons.[338] One benefit is the fact that new pharmaceutical advances provide competition for originally existing medications, decreasing the price of these medications.[339] Arguably, and even more importantly, these benefits will collectively result in better health results.[340] "One of the primary advantages of the development of follow-on drugs is the price competition that results from multiple drugs in a single therapeutic class".[341] So, if incremental innovation results in more innovation, increasing competition and creating more competitive

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[330] Steven Globerman & Kristina M Lybecker "The Benefits of Incremental Innovation: Focus on the Pharmaceutical Industry" (2014) Fraser Institute 1 at 23.
[331] Globerman & Lybecker, above n 330, at 23.
[332] Globerman & Lybecker, above n 330, at 28.
[333] Kendrick, above n 130, at 64.
[334] Kendrick, above n 130, at 64.
[335] Globerman & Lybecker, above n 330, at 23.
[336] Globerman & Lybecker, above n 330, at 24.
[337] Kendrick, above n 130, at 64.
[338] Globerman & Lybecker, above n 330, at 25.
[339] Globerman & Lybecker, above n 330, at 25.
[340] Globerman & Lybecker, above n 330, at 26.
[341] Globerman & Lybecker, above n 330, at 30.

drug prices, this will benefit healthcare users and society economically. If New Zealand adopted a DoE, this chain of events would subside due to the inability to incrementally innovate in the presence of a DoE. Allowing incremental innovation would undoubtedly "constrain the 'monopoly power of patented drugs'".[342]

Allowing incremental innovation to occur will increase pharmaceutical innovation, "increase price competition and lower launch prices … convey[ing] significant savings to patients".[343] The issue of unaffordable healthcare as it stems from exorbitant pharmaceutical prices is present in both the developing and in the developed world, [344] thus New Zealand too experiences this. Further, only "23.5% of modern medicines registered in New Zealand are publicly funded", compared to 84.3% in the UK.[345] New Zealand is also far behind Australia, which has public funding for 46.4% of its registered medicines.[346] The need for affordable healthcare in New Zealand is imperative, especially considering that out of 20 OECD countries, New Zealand has the lowest rates of access to drugs and therapies. Consequently, healthcare consumers face expensive healthcare bills, the necessary price of receiving care, "or do without" healthcare.[347] When generic drugs enter the market, healthcare users can find treatment programmes more financially suitable to them and will more readily invest in their health.[348]

Rejecting the application of *Actavis* in New Zealand will hardly mean that pharmaceutical innovators will copy one another because patent registrability criteria must still be met,[349] thus only incrementally invented therapies that "are valid and well deserved" will be patented.[350] This will not change in a patent system absent of a DoE. Therefore, "policy makers should be particularly wary of any restrictive policies that exclude incremental innovation from intellectual property protection",[351] and the DoE is one such restrictive policy to be cautious of.

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[342] Elizabeth Siew Kuan Ng, "Balancing Patents and Access to Medicine" (2009) 21 SALJ 457 at [23].
[343] Globerman & Lybecker, above n 330, at 31.
[344] Siew Kuan Ng, above n 342, at [36].
[345] "Comparable Countries" Medicines New Zealand <www.medicinesnz.co.nz>.
[346] "Comparable Countries", above n 345.
[347] Siew Kuan Ng, above n 342, at [36].
[348] Globerman & Lybecker, above n 330, at 25.
[349] Patents Act, s 14.
[350] Globerman & Lybecker, above n 330, at 36.
[351] Globerman & Lybecker, above n 330, at 49.

Concerns about the DoE in New Zealand are particularly topical given the current instability that has arisen in light of the COVID-19 pandemic. On the whole, vaccines designed to prevent the spread of diseases fail on the profitability front when compared with pharmaceuticals that are developed to manage the presence of a health condition in a patient.[352] The COVID-19 pandemic is an exemplary representation of the costs to society of low research and innovation rates in the vaccine arena.[353] Research and development efforts of vaccines to combat the COVID-19 pandemic were often ceased in the early times of COVID-19 due to it being deemed "insufficiently profitable".[354] In saying that, efforts to develop COVID-19 vaccines have increased at speed, likely due to the sheer number of people affected by COVID-19.[355] Although, by adding a DoE to patent law that can extensively protect innovation efforts, vaccine innovation will likely be further thwarted as innovators face increased uncertainty.

[352] Qiwei Claire Xue & Lisa Larrimore Ouellette "Innovation Policy and the Market for Vaccines" (2020) 7 JLB 1 at 36.
[353] Xue & Ouellette, above n 352, at 40.
[354] Xue & Ouellette, above n 352, at 40-41.
[355] Ana Santos Rutschman "The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation" (2021) 64 WUJLP 167 at 176.

7.0 Conclusion

The UKSC decision in *Actavis* was a significant departure from the settled approach to infringement interpretation in the UK. *Actavis* signaled a shift away from purposive construction as coined in *Catnic* and supplemented by the three *Improver* questions. Since the 2017 decision in *Actavis*, the approach to patent infringement is a two-step approach involving questions of textual infringement and infringement under a DoE.[356] The focus of this dissertation was to investigate the impact of *Actavis* on patent infringement, drawing on approaches and responses to the DoE in overseas jurisdictions. Then, focusing on the principles of patent law, and evaluating the arguments for and against a DoE, this dissertation determines whether or not New Zealand should adopt a DoE. Arguably, finding patent infringement via the DoE will lead to broad patent scope which will result in large monopolies, the very thing the Statute of Monopolies was enacted to prevent.[357]

The US and Germany both have a well-established DoE in their patent systems. However, the US DoE has been subject to a great deal of judicial intervention in an attempt to narrow its the confines,[358] while the German approach has a strong focus on rewarding innovation.[359] Slightly closer to home, Australian scholars are skeptical of the impact that a DoE will have on innovation.[360] Also, the Singapore Court of Appeal declined to introduce a DoE into Singapore patent law, fearful of it undermining the strict approach that Singapore employs in unilateral contracts.[361]

I assert that New Zealand should not adopt a DoE for a number of reasons that are primarily centered around the idea that a DoE will expand the scope of a patent and will create injurious monopolies. Firstly, the UKSC primarily introduced a DoE in order to comply with the UK's obligation to the EPC, to which New Zealand is not a party. Secondly, jurisdictions that have employed a DoE for some time have experienced ample judicial intervention to limit the DoE, as seen in the US.[362] Thirdly, the DoE could result in hindsight claim modifications, widening

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[356] *Actavis* (SC), above n 1, at [54].
[357] Sumpter, above n 9, at 279.
[358] Bryan, above n 237, at [42].
[359] Pechhold, above n 178, at 421.
[360] Lawrence, above 227, at 215.
[361] Bryan, above n 237, at [6].
[362] Bryan, above n 237, at [42].

patent scope and potentially encroaching upon the prior art.[363] Fourthly, the DoE can lead to inherent uncertainty in patent infringement cases, making it difficult for innovators to confidently innovate around existing patents.[364] Finally, the DoE can also adversely impact incremental innovation, the primary method of researching and developing pharmaceuticals and therapies. Therefore, given the potential for the DoE to thwart innovation, New Zealand should refrain from adopting a DoE to ensure that it does not fall into the same monopoly-creating trap that other jurisdictions have.

[363] Jamieson, above n 84, at 153.
[364] Cianfrani, above n 129, at [29].

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