

RELUCTANCE REALISED? EMERGING PROBLEMS WITH S 117(2)(B) OF THE PATENTS ACT 1990 (CTH)

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The orthodox conception of patent infringement is that a party is liable for its own infringing conduct. However, various forms of infringement exist in Australian patent law that extend liability to those who do not exploit patented inventions themselves. This includes 'supply infringement' which, in certain circumstances, creates infringement liability in the supply of products. Compared to equivalent provisions in the UK and US, Australia was quite late in creating statutory causes of action for supply infringement. Under s 117 of the Patents Act 1990 (Cth), supply infringement was always designed to extend the bounds of what constituted infringing conduct. However, when the current operation of s 117(2)(b) is examined with regard to the reasons why Australian lawmakers were reluctant to legislate supply infringement, the provision may extend too far. This undermines the legislative intent behind the introduction of the provision and has significant ramifications for the pharmaceutical industry. In particular, it has capacity to increase public expenditure on drugs, and creates uncertainty in drug development strategies. This article concludes by briefly addressing possible solutions to these problems and articulating considerations relevant to future reform.

I INTRODUCTION

A fundamental policy objective of intellectual property regimes is that the award of exclusive rights, together with the ability to enforce them, incentivises society-benefiting private activity. In patent law, exclusive rights incentivise invention and innovation. However, if patent rights extend too far, patent holders may obtain monopoly rights extending beyond the invention disclosed by the patent, and parties may be held liable for infringement unjustifiably. A balance must be reached. In the context of 'supply infringement', also known as 'indirect infringement' or 'contributory infringement',¹ achieving this balance

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1 For the purposes of this article, 'supply infringement' will be referred to as infringement under s 117 of the *Patents Act 1990* (Cth). 'Indirect infringement' will be used as a catch-all phrase for anything that is not infringement by exploitation, including supply infringement. The phrase 'contributory infringement', as far as possible, will not be used because it is often confusing. See *Akamai Technologies Inc v Limelight Networks Inc*, 692 F 3d 1301, 1341 (Fed Cir, 2012); Ann Dufty, *Report to the Industrial Property Advisory Committee* (Monash University Law School, 1983) vol 1, 208 ('*Monash Report*').

is particularly difficult. This article revisits traditional concerns with supply infringement, outlining manifestations of these concerns in its current operation.

The concept of ‘infringement’ is not specifically defined in Australian patent legislation: the *Patents Act 1990* (Cth) (*‘Patents Act’*). Section 13(1) confers on patentees ‘the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention’.² ‘Exploit’ is defined in the *Patents Act* to include:

- (a) where the invention is a product — make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- (b) where the invention is a method or process — use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.³

Accordingly, anyone who is not a patentee, or licensed by a patentee, and ‘exploits’ an invention claimed in a patent is an infringer. This type of infringer is commonly known as a ‘direct infringer’. However, since the term ‘direct infringement’ also refers to ‘authorising’ another party to infringe a patent,⁴ this article will refer to a party that ‘exploits’ an invention as an ‘infringer by exploitation’.

Liability may also attach on a common law basis to a person who becomes a joint tortfeasor by procuring or inducing infringement,⁵ or engaging in a common design with an infringer.⁶ In that context, s 117 of the *Patents Act* introduces a further liability which arises out of the ‘supply’ of products. When supply infringement was introduced into Australian patent law with the enactment of the *Patents Act*, it created liability in supply of non-patented goods when the use of those goods, in certain scenarios, would infringe exclusive rights by customers. This article draws quite heavily on the precise wording of s 117. It is therefore necessary to quote the section in full:

- (1) If the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement of the patent by the supplier unless the supplier is the patentee or licensee of the patent.

2 *Patents Act* s 13(1).

3 *Ibid* sch 1 (definition of ‘exploit’).

4 *Blueport Nominees Pty Ltd v Sewerage Management Services Pty Ltd* [2015] FCA 631 (24 June 2015) [85].

5 *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 164 ALR 239, 258–9 [41] (*‘Ramset’*); *Danisco AS v Novozymes AS (No 2)* (2011) 91 IPR 209, 244–6 [159]–[167]; *Damorgold Pty Ltd v Jai Products Pty Ltd* (2014) 105 IPR 60, 72 [82]–[87]. For the purposes of this article, this cause of action will be referred to as ‘procured infringement’.

6 *SNF (Australia) Pty Ltd v Ciba Specialty Chemicals Water Treatments Ltd* (2011) 92 IPR 46, 115–16 [310]–[313] (*‘SNF’*); *Bayer Pharma Aktiengesellschaft v Genentech Inc* (2012) 98 IPR 424, 428–32 [23]–[38]; *Morton-Norwich Products v Intercen Ltd* [1978] RPC 501.

- (2) A reference in subsection (1) to the use of a product by a person is a reference to:
- (a) if the product is capable of only one reasonable use, having regard to its nature or design — that use; or
 - (b) if the product is not a staple commercial product — any use of the product, if the supplier had reason to believe that the person would put it to that use; or
 - (c) in any case — the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.

The focus of this article is the current operation of s 117(2)(b). Compared to other common law nations, the Australian legislature was later than others in creating statutory causes of action for supply infringement. Analogous US legislation was enacted in 1952,⁷ and UK legislation in 1977.⁸ Professor Ann Monotti has outlined three reasons why Australia was ‘reluctant’ to recognise supply infringement, namely: it can convert the sale of an unpatented product into an infringing action; it enables tying and patent misuse; and it creates a supplementary cause of action for infringement.⁹

This article examines four recent cases on the operation of s 117(2)(b) using Monotti’s three reasons. Although most of these reasons are self-explanatory or known terms in Australian law, ‘patent misuse’ requires a brief introduction. During the first half of the 20th century in the US, common law based indirect infringement law was used to extend patent rights to broadly cover non-patented products.¹⁰ In response to this, the equitable doctrine of patent misuse developed, which operates as a defence to infringement.¹¹ In a nutshell, it requires showing that the patentee has misused their patent rights by unfairly extending them to suppress competition beyond the patent rights granted.¹²

Supply infringement relating to pharmaceutical patents forms a key component of this article. Case law on the operation of s 117(2)(b) predominantly involves pharmaceutical drugs, and the outcomes of these cases could have profound effects on social, economic and innovative endeavours. A key component of this litigation is that new patented uses of known drugs, commonly known as patents

7 *Patent Act of 1952*, 35 USC § 271 (1952).

8 *Patents Act 1977* (UK) c 37, ss 60(2)–(3).

9 Ann Monotti, ‘Contributory Infringement of a Process Patent under the *Patents Act 1990*: Does It Exist After Rescare?’ (1995) 6 *Australian Intellectual Property Journal* 217, 220–1.

10 Donald S Chisum, *Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement* (LexisNexis, vol 6A, 2014) § 17.02–17.02[6], § 19.04[1][b].

11 *Ibid* § 19.04[1][b].

12 *Ibid* § 19.04. See generally Mark A Lemley, ‘The Economic Irrationality of the Patent Misuse Doctrine’ (1990) 78 *California Law Review* 1599, 1608–10.

for ‘secondary medical indications’,¹³ present examples of where the supply of an unpatented drug can result in the infringement of a method of use patent.¹⁴ When Monotti’s first two reasons are examined cognisant of current Australian case law and US jurisprudence, certain problems with s 117(2)(b) appear quite clearly. It is argued that the provision permits a type of statutory patent misuse that enables evergreening, and foreclosure of markets that should be open to generic competition.

On Monotti’s third reason, originally, the reluctance was that patentees already had a cause of action against infringers by exploitation, and did not need another. However, difficulties in pursuing infringers by exploitation when they may be numerous and widely spread, and the fact that financial relief in individual instances may be small, meant that supply infringement was a practical economic compromise.¹⁵ Notwithstanding the availability of supply infringement, other types of patent infringement have continued to develop, both under statute and under common law.¹⁶ In particular, these actions raise the prospect that doctors and pharmacists may be liable for their role in prescribing or dispensing drugs and, as explored below, in some circumstances are perhaps more culpable for infringement of patented secondary medical indications.

This article is divided into four main parts. Part II details the formation of s 117. Part III describes the state of play with regards to s 117(2)(b), and how it gives rise to Monotti’s first two reasons for reluctance; these two reasons are addressed together because they are complementary. Part IV assesses the legal background to other relevant patent infringement actions, and analyses them from the perspective of Monotti’s third reason for reluctance. Parts III and IV together illustrate that Monotti’s three reasons for reluctance are beginning to be realised.

During the discussion of the formation of s 117(2)(b) in pt II, government justifications for implementing s 117 are elucidated. It is beyond the scope of this work to exhaustively consider the government’s rationale, however, where the analysis of Monotti’s reasons for reluctance are relevant to the government’s justifications, some comments are made. As a whole, this article argues that s 117(2)(b) may not be operating as intended or desired, extending patent rights too far, and enabling liability to be found in parties that play a remote role in infringement by exploitation. The final part of this article addresses possible solutions to the problems posed by s 117(2)(b) and outlines considerations for future law reform.

13 William van Caenegem, ‘Infringement of Patents for New Uses of Known Drugs: Lessons from Recent Cases’ (2013) 25 *Australian Intellectual Property Law Bulletin* 187, 187, 190.

14 That a method of medical treatment using a drug is a patentable subject matter was confirmed by the High Court in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 304 ALR 1, 46–7 [160]–[165] (Hayne J), 71–3 [276]–[288] (Crennan and Kiefel JJ) (*‘Sanofi’*).

15 Monotti, ‘Contributory Infringement of a Process Patent’, above n 9, 220–1. For an instructive explanation with reference to copyright, see Douglas Lichtman and William Landes, ‘Indirect Liability for Copyright Infringement: An Economic Perspective’ (2003) 16 *Harvard Journal of Law & Technology* 395, 395–8.

16 See below pt IV. See also Ann L Monotti, ‘Infringement of a Patent by Authorisation: Clear or Muddy Waters?’ (2013) 24 *Australian Intellectual Property Journal* 5, 6–8.

II FORMATION

The move towards enacting a provision in Australian patent law addressing supply infringement began in 1979 when the then Minister for Productivity asked the Industrial Property Advisory Committee ('IPAC') to review the patent system.¹⁷ Recommendation 33 of the *Patents in Australia Report* concluded that:

in general the supply of goods whose only use would infringe a patent, or which are accompanied by a positive inducement for the ultimate consumer to perform actions which would innocently or knowingly infringe a patent, should itself be an infringement of the patent.¹⁸

The Government accepted Recommendation 33. It noted that '[t]he introduction of provisions to deal with contributory infringement will remove an area of uncertainty under Australian patent law and harmonise it with the laws of Australia's major trading partners'.¹⁹

The section of the Explanatory Memorandum for the *Patents Act* that addressed supply infringement was quite brief. It stated, '[t]he intent of this clause is to implement the Government's response to recommendation 33 of the Industrial Property Advisory Committee relating to indirect or contributory infringement'.²⁰ After quoting Recommendation 33 from the *Patents in Australia Report*, the Explanatory Memorandum described the three subsections that would constitute supply infringement under ss 117(2)(a)–(c).

From this material it can be observed that only ss 117(2)(a) and (c) were specifically endorsed by the *Patents in Australia Report*. That is, supply of a product that only has one reasonable use and supply accompanied with inducement. There was no endorsement of a s 117(2)(b) type action. Section 117(2)(b) was only mentioned in the Explanatory Memorandum when outlining the whole provision. No rationale was specifically provided for adding this provision to the two provisions recommended in the *Patents in Australia Report*. This inconsistency has been observed by Hayne J in *Northern Territory v Collins* ('*Collins*')²¹ when his Honour stated:

the Explanatory Memorandum to the 1990 Bill saw no incongruity between [IPAC's] recommendations and the addition of reference to 'any use of a non-staple commercial product to which the supplier had reason to believe that the receiver would put it'.²²

17 *Monash Report*, above n 1, iii.

18 Industrial Property Advisory Committee, Parliament of Australia, *Patents, Innovation and Competition in Australia*, (1984) 67 ('*Patents in Australia Report*').

19 Statement by the Minister for Science, 'Government Response to the Report of the Industrial Property Advisory Committee, "Patents, Innovation and Competition in Australia"' (1986) 56 *Official Journal of Patents, Trade Marks and Designs* 1462, 1477.

20 Explanatory Memorandum, Patents Bill 1990 (Cth) 28 [170].

21 (2008) 235 CLR 619.

22 *Ibid* 631 [45], quoting Explanatory Memorandum, Patents Bill 1990 (Cth) 28 [170].

Although the *Patents in Australia Report* did not canvass s 117(2)(b), it did outline a rationale for supply infringement more generally, stating that it was:

unreasonable and wasteful of resources for a patentee to have to sue all of the [infringers by exploitation] with so unsatisfactory a result in each case, when the supplier is, in a real sense, far more responsible for the commission of the infringing acts.

We believe that it would be more effective, realistic and just for the patentee to be able to take action against the supplier or middleman who facilitates the commission of the infringing act by the ultimate consumer.²³

If IPAC's rationale is combined with those in the Government Response to Recommendation 33, justifications for implementing s 117 can be distilled down to three reasons: a 'more effective, realistic and just'²⁴ enforcement system; international harmonisation; and certainty.

Shortly after the *Patents Act* and associated regulations came into effect, various sources criticised the way they were drafted and the drafting process itself. In 1986, a working party was appointed by the Commissioner of Patents to help give effect to the *Patents in Australia Report*. The ad hoc working party included members from the Law Council, the Institute of Patent Attorneys, the Patents Office, as well as Parliamentary drafters. Professor Sam Ricketson has commented that during drafting, 'suggestions from the working party were often rejected or ignored by the Parliamentary Draftsman.'²⁵ Separately, Crispin Marsh criticised the *Patents Act* for being a 'seriously flawed attempt to address the legitimate need for legislative reform'.²⁶ Similarly, Terrence Collins in his 1991 address as President of the Institute of Patent Attorneys, commented that 'a different person drafts the Bill and the Regulations respectively, and in each case policy requires that the draftsmen work from instructions which convey the intent, but not possible form, of the legislation. The process is therefore cumbersome and fraught with peril'.²⁷ Whilst none of these commentators turned their attention to s 117, their comments, combined with the lack of specific justification for s 117(2)(b), do indicate that perhaps the subsection has not received the attention that it warrants.

23 *Patents in Australia Report*, above n 18, 67. This also overlaps with the orthodox economic rationale for indirect copyright infringement, see William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press, 2003) 118–19; Lichtman and Landes, above n 15, 395–8.

24 *Patents in Australia Report*, above n 18, 67.

25 Sam Ricketson, 'The Future of Australian Intellectual Property Law Reform and Administration' (1992) 3 *Australian Intellectual Property Journal* 3, 21.

26 Crispin Marsh, 'The Patents Act 1990 — Is the Tail of Bureaucratic Convenience Wagging the Legislative Dog?' (1993) 4 *Australian Intellectual Property Journal* 142, 142.

27 Terrence J Collins, 'Seventy-Second Annual General Meeting Presidential Address' (Speech delivered at the 72nd Annual General Meeting of the Institute of Patent and Trade Mark Attorneys of Australia, 13 April 1991).

III CONVERSION OF UNPATENTED PRODUCTS INTO AN INFRINGEMENT OF A PROCESS CLAIM AND STATUTORY PATENT MISUSE

A State of Play

Since, as the High Court has recently confirmed, the actual text is the primary consideration in issues of statutory interpretation,²⁸ any consideration must start with the text of s 117. Assuming use of a supplied product by a person constitutes infringement, there are two key requirements that must be satisfied to prove supply infringement under s 117(2)(b). First, the product supplied must not be a ‘staple commercial product’, and second, ‘the supplier had a reason to believe that the person would’ put it to the infringing use.²⁹

The term, ‘staple commercial product’ is not defined in the *Patents Act*, but it has been interpreted by the High Court in *Collins*. Gummow ACJ and Kirby J in a joint judgment, adopted part of French J’s discussion of ‘staple commercial products’ from his preceding Full Federal Court decision.³⁰ Specifically, Gummow ACJ and Kirby J adopted the part of French J’s judgment that concluded unmilled timber was a staple commercial product because it had a ‘variety of applications’.³¹ In the other High Court judgments, Crennan J stated that the ‘relevant inquiry is into whether the supply of the product is commercial and whether the product has various uses’.³² Hayne J agreed with Crennan J on this point, and Heydon J agreed with Crennan J’s entire judgment.³³ Accordingly, since *Collins*, courts have concluded that a ‘staple commercial product’ is one that is supplied for a variety of applications.³⁴

There are four recent cases relevant to the supply of pharmaceuticals that are illustrative of Monotti’s reasons for reluctance. They are: *Sanofi*,³⁵ *Warner-*

28 *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue (NT)* (2009) 239 CLR 27, 46–7 [47].

29 *Patents Act* s 117(2)(b).

30 *Collins* (2008) 235 CLR 619, 625–7 [23]–[27], citing *Collins v Northern Territory* (2007) 161 FCR 549, 564–70 [37]–[52], 582–3 [97]–[100].

31 *Collins* (2008) 235 CLR 619, 626 [27], quoting *Collins v Northern Territory* (2007) 161 FCR 549, 582–3 [99].

32 *Collins* (2008) 235 CLR 619, 653–4 [145].

33 *Ibid* 630 [41] (Hayne J), 634 [57] (Heydon J).

34 See, eg, *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* (2012) 291 ALR 763, 778–9 [90]–[91] (Yates J); *Generic Health Pty Ltd v Otsuka Pharmaceutical Co Ltd* (2013) 296 ALR 50, 65 [63] (Bennett J) (*Generic Health*); *Apotex Pty Ltd v AstraZeneca AB [No 4]* (2013) 100 IPR 285, 410–11 [511] (Jagot J) (*Apotex*); *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324, 417–8 [428]–[431] (Besanko, Foster, Nicholas and Yates JJ) (*AstraZeneca*); *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd (No 4)* [2015] FCA 634 (29 June 2015) [186]–[189] (Yates J) (*Otsuka*).

35 (2013) 304 ALR 1.

Lambert Co LLC v Apotex Pty Ltd ('Lambert'),³⁶ *AstraZeneca*,³⁷ and *Otsuka*.³⁸ Professor William van Caenegem has previously discussed the outcome of the Full Federal Court's decision in the interlocutory case preceding *Otsuka*, as well as the Full Federal Court judgments preceding the High Court's decision in *Sanofi*, and the first instance trial decision preceding the Full Federal Court's decision in *AstraZeneca*.³⁹ The analyses here will build on his brief commentary.

Before moving on it should be noted that *Otsuka* is a trial decision now on appeal,⁴⁰ and *Lambert* is an appeal decision by the Full Federal Court on an interlocutory injunction and the first instance trial was heard in July 2015.⁴¹ While there is merit in waiting for the full resolution of all these disputes, that may take years and these decisions are likely to be currently affecting legal advice and markets for pharmaceuticals.

The cases provide guidance on how the High Court's interpretation of staple commercial products applies to pharmaceuticals. In the first instance decision preceding *AstraZeneca*, Jagot J held that although the drug in question, rosuvastatin, was used to reduce the incidence of plaque rupture and heart attacks, as well as treat diabetes, stroke, chronic renal disease, coronary artery disease, peripheral vascular disease and hypercholesterolemia,⁴² it was not a staple commercial product.⁴³ Her Honour stated:

While 'staple' is not concerned with the economic significance of uses, it is concerned with the variety of uses. The variety of uses in this case is confined by the nature of the product to a limited class, being the treatment of diseases of a particular kind or class (albeit different diseases) in humans. Rosuvastatin, despite its usefulness for a variety of disease conditions, is not able to be compared to timber (as in *Collins*) or, for example, types of pharmaceutical products which might be useful for many human conditions.⁴⁴

On appeal, the Full Federal Court generally agreed with Jagot J's reasoning that rosuvastatin is not a staple commercial product,⁴⁵ adding further that 'uses to which rosuvastatin may be put appear to us to be limited to the prevention or treatment of cardiovascular disease and its associated risk factors (for example, high cholesterol)'.⁴⁶ Cardiovascular disease itself refers to diseases that affect the

36 (2014) 311 ALR 632.

37 (2014) 226 FCR 324. This decision was appealed, but not on the issue of supply infringement, see, *AstraZeneca AB v Apotex Pty Ltd* (2015) 89 ALJR 798.

38 [2015] FCA 634 (29 June 2015).

39 Van Caenegem, above n 13. See generally *Generic Health* (2013) 296 ALR 50; *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [No 2]* (2012) 204 FCR 494; *Apotex* (2013) 100 IPR 285.

40 *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* NSD837/2015.

41 *Apotex Pty Limited v Warner-Lambert Company LLC* NSD763/2013.

42 *Apotex* (2013) 100 IPR 285, 408–9 [502].

43 *Ibid* 410–11 [511].

44 *Ibid*.

45 *AstraZeneca* (2014) 226 FCR 324, 418–19 [431]–[433].

46 *Ibid* 418 [431].

cardiovascular system, particularly heart and blood vessels.⁴⁷ The Full Federal Court also specified that the prescription of rosuvastatin for non-cardiovascular diseases, for example, diabetes, was to prevent or treat cardiovascular disease in situations where there was increased risk of it occurring.⁴⁸ Thus, this use was for treating or preventing cardiovascular disease and not diabetes (or another non-cardiovascular disease) per se. Distilling this reasoning down, it appears that treating or preventing a range of diseases that fall within the class of cardiovascular disease is not in itself broad enough for a product to be considered a staple commercial product.

The findings in *AstraZeneca* are consistent with those in *Sanofi*, *Lambert* and *Otsuka*. In all three cases the drugs in question were found not to be staple commercial products.⁴⁹ This suggests that, as a general rule, pharmaceutical drugs do not qualify as staple commercial products and are therefore open to s 117(2)(b) infringement.

The second requirement of s 117(2)(b) is whether the supplier has reason to believe that a person would use a supplied drug for an infringing purpose. The Full Federal Court has unanimously concluded this is an objective test,⁵⁰ the issue being whether ‘a reasonable person in the position of [the supplier] would have reason to hold such a belief’.⁵¹ Bennett J has expanded on this point stating:

The question that arises in this application is the meaning to be attributed to the phrase ‘reason to believe that the person would put it to that use’. The reason to believe is that of the supplier and may be subjective: an actual belief, or objective: that there are reasonable grounds to believe. In each case, the belief is determined on the balance of probabilities. ... The proper construction of s 117(b) must be that there is a reasonable belief of a significant likelihood that a person will put a product to that use. This construction is assisted by the use of the words ‘reasonable belief’, rather than ‘knowledge’. A person may have a reasonable belief that an event will or would happen without having knowledge that the event will or would necessarily happen. A reasonable belief that an event would happen arises from a belief in the likelihood of that event. That likelihood must be significant. A belief that an event is of a low likelihood would amount to a

47 World Health Organization Regional Office for Europe, *Definition of Cardiovascular Diseases* (2015) <<http://www.euro.who.int/en/health-topics/noncommunicable-diseases/cardiovascular-diseases/cardiovascular-diseases2/definition-of-cardiovascular-diseases>>; Australian Government Department of Health, *What is Cardiovascular Disease?* (14 January 2015) <<http://www.health.gov.au/internet/main/publishing.nsf/Content/chronic-cardio#wha>>.

48 *AstraZeneca* (2014) 226 FCR 324, 418 [431].

49 Leflunomide was found not to be a staple commercial product in *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd [No 3]* (2011) 196 FCR 1, 79 [270], this was not pursued on appeal in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [No 2]* (2012) 204 FCR 494, 528 [147]. Aripiprazole was found not to be a staple commercial product in *Otsuka* [2015] FCA 634 (29 June 2015) [182]–[191]. For the purposes of an interlocutory injunction pregabalin was accepted not to be a staple commercial product in *Lambert* (2014) 311 ALR 632, 637 [27].

50 *Generic Health* (2013) 296 ALR 50, 59 [34]–[35] (Emmett J), 73–4 [103]–[106] (Bennett J), 90 [229] (Greenwood J).

51 *Ibid* 59 [35] (Emmett J).

reasonable belief that the event *may* happen. The word used by s 117(b) is that that a person *would* put the product to that use.⁵²

In *Sanofi*, the patentees held exclusive rights to the use of leflunomide for the treatment of psoriasis.⁵³ The generic company in this case registered leflunomide for the purposes of treating psoriatic arthritis and rheumatoid arthritis.⁵⁴ Treating both types of arthritis with leflunomide were listed on the Australian Register of Therapeutic Goods ('ARTG'), but treatment of psoriasis alone was not.⁵⁵ Nevertheless, an important fact to the case was that psoriasis is a diagnostic symptom of arthritis and arises in virtually every incidence of psoriatic arthritis.⁵⁶

Although the generic company specifically stated on the product label that it was not to be used for the patented purpose, the patent holders argued that by treating psoriatic arthritis, psoriasis was being treated as well, that this fact would be known by the supplier, and therefore the circumstances gave rise to a 'reason to believe'.⁵⁷

At first instance, Jagot J found infringement under s 117(2)(b) because treatment of psoriatic arthritis would by necessity treat psoriasis as well.⁵⁸ In the Full Federal Court, Bennett and Yates JJ in a joint judgment deferred to Jagot J's findings,⁵⁹ while Keane CJ found infringement but via a different route. Although Keane CJ interpreted the patentee's claim to be specifically limited to the treatment or prevention of psoriasis, and therefore not infringed when treating psoriatic arthritis,⁶⁰ he nevertheless found infringement under s 117(2)(b) based on the information provided with the generic leflunomide. The product information documentation ('PID') associated with generic leflunomide stated, '[generic] [l]eflunomide is not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease'.⁶¹ Keane CJ concluded that this statement, combined with the medical knowledge that leflunomide does treat psoriasis, would give rise to ample reason to believe that leflunomide would be used to treat psoriasis associated with psoriatic arthritis.⁶²

In the High Court,⁶³ the finding of no infringement was unanimous. In Crennan and Kiefel JJ's joint judgment, their Honours emphasised two aspects of the case that led to this finding. First, that no evidence was adduced that demonstrated

52 Ibid 73–4 [103]–[106]. It should also be noted that in *AstraZeneca* (2014) 226 FCR 324, 419 [433] (Besanko, Foster, Nicholas and Yates JJ), 97 (Jessup J agreeing), the Full Federal Court rejected the contention that a patentee must prove a particular person or persons will put the product supplied to an infringing use.

53 (2013) 304 ALR 1, 4 [3].

54 Ibid 4 [4].

55 Ibid 25 [60]–[61].

56 Ibid 50 [182].

57 *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd* [No 3] (2011) 196 FCR 1, 34–35 [138].

58 Ibid 77 [263].

59 *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [No 2] (2012) 204 FCR 494, 528–30 [147]–[155].

60 Ibid 504 [37].

61 *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd* [No 3] (2011) 196 FCR 1, 76 [261].

62 *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [No 2] (2012) 204 FCR 494, 508–9 [52]–[53].

63 *Sanofi* (2013) 304 ALR 1.

doctors prescribed leflunomide for the purposes of treating psoriasis alone;⁶⁴ and second, that the *Therapeutic Goods Act 1989* (Cth) ('TGA'), in particular s 16, stipulated that '[t]herapeutic goods ... are taken to be separate and distinct from other therapeutic goods if they have ... "different indications" ... or "different directions for use"'.⁶⁵ Taking into account the specific exclusion on the PID, Crennan and Kiefel JJ rejected Keane CJ's and Jagot J's logic underpinning their finding of infringement, stating:

[Generic leflunomide] is a therapeutic good registered for its indicated uses, which specifically exclude [the infringing use]. In light of the provisions of the TGA, to which reference has been made, the expression 'indication' in the product information document is an emphatic instruction to recipients of [generic leflunomide] to restrict use of the product to uses other than [the infringing use asserted].⁶⁶

As a result Crennan and Kiefel JJ concluded that:

For the purposes of the application of s 117(2)(b), it was not shown, nor could it be inferred, that [a generic company] had reason to believe that the unpatented pharmaceutical substance, ... would be used by recipients in accordance with the patented method, contrary to the indications ... approved [on the] product information document.⁶⁷

French CJ and Gageler J wrote separate judgments but both agreed with Crennan and Kiefel JJ's reasoning on infringement.⁶⁸ On this point, Hayne J arrived at the same outcome via similar reasoning.⁶⁹

Commentary has mooted whether the unanimous findings in *Sanofi* may be a 'rubberstamp' for generic pharmaceutical companies to supply drugs that could be put to infringing uses, if labels state the drug is only to be used for non-infringing purposes and exclude other uses.⁷⁰ However, as demonstrated in *Lambert*, this does not appear to be the case.

In *Lambert*, the patentees controlled rights to the use of pregabalin to treat pain.⁷¹ At the time there were two ARTG listings for pregabalin, one for pain and another for seizures.⁷² A generic company obtained approval for use of pregabalin

64 Ibid 50 [182].

65 TGA s 16(1)(e)–(f), cited in *Sanofi* (2013) 304 ALR 1, 75 [296].

66 *Sanofi* (2013) 304 ALR 1, 76 [303].

67 Ibid 76–7 [304].

68 Ibid 23 [51] (French CJ), 79 [316] (Gageler J).

69 Ibid 48–9 [168]–[172].

70 Matthew Swinn and David Fixler, *The High Court Gives Generics the Rubber-Stamp for 'Skinny Labelling' (But No Surprises on Method of Treatment Patents)* (5 February 2014) Corrs Chambers Westgarth <<http://www.corrs.com.au/publications/corrs-in-brief/the-high-court-gives-generics-the-rubber-stamp-for-skinny-labelling-but-no-surprises-on-method-of-treatment-patents/>>.

71 (2014) 311 ALR 632, 633 [1].

72 Ibid 634 [8].

in seizures and went to launch the product.⁷³ As part of the launch the generic company proposed sending letters to doctors and pharmacists instructing them not to prescribe or dispense pregabalin to treat pain.⁷⁴ Nevertheless, the patent holders alleged that generic pregabalin would be used ‘off-label’ for the patented use of treating pain.⁷⁵ ‘Off-label’ use of drugs is a term used to describe the prescription of drugs outside of marketing approval by a marketing body.⁷⁶

Before continuing commentary on this case, it is necessary to briefly outline key aspects of pharmaceutical prescription and dispensing in Australia. Doctors often prescribe drugs without direct reference to medical information for which a drug is approved. They will rely on information from various sources and their clinical experience when doing so. A consequence of this is that sometimes doctors write prescriptions for drugs that are not approved for the specific purpose for which they are being prescribed.⁷⁷ Moreover, as the reasons drugs are prescribed are not usually written on the prescription, this means a pharmacist later dispensing a drug will not necessarily know the reason why a drug is dispensed. When dispensing, pharmacists (by various means) are entitled to supply alternative brands of drugs if patients are consulted.⁷⁸ As pharmacists are usually aware of bio-equivalence between brands of drugs (it is part of their profession), it is not difficult to see how generic drugs could be supplied for infringing ‘off-label’ purposes.⁷⁹

At first instance in *Lambert*, Griffiths J found that, although the letters and labels limited the drug to seizures, it might still ‘be possible to establish the requisite reason to believe by reference to other evidence or the drawing of appropriate inferences’.⁸⁰ Griffiths J went on to clarify that these findings would have to overcome the ‘emphatic instructions’ not to use a drug for an infringing purpose that may arise due to specific ARTG listings and/or instructions not to use a drug for a specific purpose.⁸¹ On appeal from Griffiths J’s decision, a unanimous Full Court found that a *prima facie* case under s 117(2)(b) was made out.⁸² The

73 Ibid 635 [13]–[14]. It should be noted here that the patentees also controlled patents to the use of pregabalin for treatment of seizures, but, in this case, infringement of this patent was not pursued: at 634 [7], 635 [12].

74 *Warner-Lambert Co LLC v Apotex Pty Ltd* (2014) 106 IPR 59, 62 [12], 69–73 [52].

75 *Lambert* (2014) 311 ALR 632, 637 [25].

76 Monika K Krzyzanowska, ‘Off-Label Use of Cancer Drugs: A Benchmark Is Established’ (2013) 31 *Journal of Clinical Oncology* 1125, 1125; *Warner-Lambert Co LLC v Apotex Pty Ltd* (2014) 106 IPR 59, 63 [21].

77 See generally, Gazarian et al, ‘Off-Label Use of Medicines: Consensus Recommendations for Evaluating Appropriateness’ (2006) 185 *Medical Journal of Australia* 544, 544; Krzyzanowska, above n 76, 1125; Rena M Conti et al, ‘Prevalence of Off-Label Use and Spending in 2010 among Patent-Protected Chemotherapies in a Population-Based Cohort of Medical Oncologists’ (2013) 31 *Journal of Clinical Oncology* 1134, 1134–5; Rebecca Dresser and Joel Frader, ‘Off-Label Prescribing: A Call for Heightened Professional and Government Oversight’ (2009) 37 *Journal of Law, Medicine & Ethics* 476, 476–7.

78 *Warner-Lambert Co LLC v Apotex Pty Ltd* (2014) 106 IPR 59, 64–5 [25]–[30].

79 *Lambert* (2014) 311 ALR 632, 640–1 [39]–[42].

80 *Warner-Lambert Co LLC v Apotex Pty Ltd* (2014) 106 IPR 59, 77 [63].

81 Ibid 80 [74].

82 *Lambert* (2014) 311 ALR 632, 651–2 [89]–[94].

Court put weight on testimony suggesting that despite the letters and the ARTG listing for the generic product, pharmacists would substitute a generic version of the drug in infringing circumstances and there were no ethical or professional standards prohibiting this.⁸³ As a result it appears that *Sanofi* may be a hurdle rather than a ‘rubberstamp’.

The Full Federal Court appeal in *AstraZeneca*, was before a rare five member bench.⁸⁴ The patent holders had previously achieved interlocutory success by asserting infringement of three patents against a group of generic companies.⁸⁵ However, in *Apotex*, the first instance trial before Jagot J, her Honour found that all three patents were invalid. Nevertheless, she continued to consider infringement.⁸⁶ The first patent claimed use of rosuvastatin in 5–10mg doses as a cholesterol lowering agent,⁸⁷ the second patent claimed 20–40mg doses for treating a form of hypercholesterolemia,⁸⁸ and the third claimed pharmaceutical compositions of rosuvastatin.⁸⁹ As described above, the drug in issue in this case, rosuvastatin, could be used for a variety of medical indications.⁹⁰

With regards to s 117(2)(b),⁹¹ at first instance before Jagot J, the patent holders argued that infringement could arise via two off-label mechanisms. First, it was argued that doctors would prescribe, or pharmacists dispense, packaged dosages of generic rosuvastatin for an infringing off-label use,⁹² and secondly, that doctors would prescribe, or pharmacists would dispense, dosages of generic rosuvastatin for uses that were off-label, but that to be used for the infringing purpose, the pills would have to be split.⁹³ Evidence was led of pill splitting using a cheap, handheld ‘pill-splitter’ that was commonly available in pharmacies.⁹⁴ The most likely product that would be split was the 20mg tablet.⁹⁵ It was argued it would be split into two 10mg halves for the patented use of cholesterol lowering.⁹⁶ It was

83 Ibid 641 [41]–[45], 650–1 [88]–[91].

84 *AstraZeneca* (2014) 226 FCR 324 (Besanko, Foster, Nicholas, Yates and Jessup JJ).

85 *Apotex* (2013) 100 IPR 285, 288–9 [2]–[4].

86 Ibid 392–413 [414]–[523].

87 Ibid 290–1 [6]–[7], [11].

88 Ibid 296–7 [19].

89 Ibid 301 [27].

90 Ibid 410 [509].

91 It is necessary to note that in *AstraZeneca* the generic companies were proposing to supply dosages of rosuvastatin with instructions for uses that were patent protected. This fact gives rise to infringement issues under s 117(2)(b) and (c): see *Apotex* (2013) 100 IPR 285, 409 [506]. Although s 117(2)(b) is raised, this argument is not dealt with in detail because a defendant in these circumstances can choose not to include instructions. As a result, the defendant is not necessarily foreclosed from the market.

92 *Apotex* (2013) 100 IPR 285, 411 [516].

93 Ibid 406 [489].

94 Ibid 304 [39], 406–7 [491]–[492].

95 Indeed evidence was adduced showing that prescriptions for the patent holders’ own 20mg tablet included advice to split them, the rationale here being that it would make treatment cheaper: ibid 406–7 [491]–[492].

96 Ibid 410 [508].

also argued that the reason for doctors to prescribe, or pharmacists to dispense, these off-label uses was ‘economic’, in that it was much cheaper for patients.⁹⁷

In both circumstances of off-label infringement under s 117(2)(b), Jagot J found that there was insufficient evidence that a person would put the dosages to the patent protected uses. In the circumstances of off-label use that included splitting pills, Jagot J concluded that, although the applicant had shown there was a ‘real risk’ that a person would split a tablet, such risk was insufficient.⁹⁸ With regard to same dosage off-label use, Jagot J reasoned that the ‘inference’ generic rosuvastatin would be used for patented purposes could not be drawn from the product’s associated information.⁹⁹ Jagot J did not mention any evidence that doctors would prescribe or pharmacists would dispense, same dosage generic drugs without reference to the label.¹⁰⁰ It appears that evidence was not led on this point during trial, which is interesting because in the original interlocutory judgment, Rares J appeared to put weight on such evidence.¹⁰¹

Before the five member Full Federal Court, the patent holders confined their s 117(2)(b) infringement argument to splitting the 20mg tablet for an infringing off-label use.¹⁰² The Court affirmed Jagot J’s finding that the relevant patents were invalid, but reasoned that if they were valid, supply infringement would be found.¹⁰³ On this point the Court was unanimous.¹⁰⁴ Putting weight on the facts that a pharmacist had given evidence of widespread use of tablet splitting devices and that two doctors had given prescriptions with instructions to split 20mg tablets (or had prescribed higher doses of rosuvastatin to facilitate pill splitting),¹⁰⁵ the Court found that generic companies supplying the tablets would have reason to believe that a consumer would use them for an infringing purpose.¹⁰⁶ In short, the ‘real risk’ that Jagot J originally described was sufficient.

In *Otsuka*, a pharmaceutical company registered a generic version of aripiprazole on the ARTG for the ‘treatment of schizophrenia including maintenance of clinical improvement during continuation therapy’.¹⁰⁷ Yates J found the claims relevant to supply infringement to be invalid, but continued to consider infringement.¹⁰⁸ Aripiprazole could be registered for three medical indications,¹⁰⁹ but only one that

97 Ibid 407 [492], 410 [508].

98 Ibid 411 [512].

99 Ibid 412 [517].

100 Ibid 411–12 [515]–[519].

101 *Apotex Pty Ltd v AstraZeneca AB* (2011) 94 IPR 508, 515–17 [33]–[40]. However, this statement may be open to contest as Rares J never clarified a specific form of infringement: see *Apotex Pty Ltd v AstraZeneca AB [No 2]* [2012] FCA 142, 5 [14].

102 *AstraZeneca* (2014) 226 FCR 324, 416 [425] (Besanko, Foster, Nicholas and Yates JJ).

103 Ibid 418–20 [432]–[439].

104 Ibid 416–21 [423]–[446] (Besanko, Foster, Nicholas and Yates JJ), 97 [447] (Jessup J agreeing).

105 Ibid 419 [436].

106 Ibid 420 [439].

107 *Otsuka* [2015] FCA 634 (29 June 2015) [7].

108 Ibid [14], [350].

109 Ibid [6].

pertained to treating schizophrenia.¹¹⁰ Broadly speaking there are two forms of schizophrenia, 'acute' and 'chronic'.¹¹¹ Acute schizophrenia lasts for more than six months after which a patient recovers (but may relapse).¹¹² Chronic schizophrenia lasts much longer than six months, and usually for many years.¹¹³ There are various symptoms associated with both types of schizophrenia and they are often classified into two categories: 'positive' symptoms such as hallucinations and delusions, as well as 'negative' symptoms such as apathy and poverty of thought.¹¹⁴ Yates J also found that cognitive symptoms such as cognitive impairment can be classified as another category of symptom, although his Honour did note that some experts include it as a negative symptom.¹¹⁵ 'Treatment-resistant' schizophrenia is a severe subtype of chronic schizophrenia characterised by patients' negative and positive symptoms not responding to antipsychotic medication.¹¹⁶

In the circumstances of *Otsuka*, a variety of drugs were already available to treat schizophrenia, and evidence showed that it was common for doctors to switch drugs during treatment to optimise clinical responses.¹¹⁷ Indeed, the Royal Australian and New Zealand College of Psychiatrists guidelines recommended switching if positive or negative symptoms persisted or patients experienced distressing side-effects.¹¹⁸ Relevant to the patent holder s 117(2)(b) action, the patentee controlled rights to the use of aripiprazole for the specific treatment of cognitive impairment caused by treatment-resistant schizophrenia or chronic schizophrenia, in circumstances in which a patient had failed to respond to two or more other specified drugs.¹¹⁹ The patent holders alleged infringement under s 117(2)(b) because the generic company would supply aripiprazole and they argued it would then be used in such a way that infringed these rights.¹²⁰

In examining whether the generic company would have a 'reason to believe', Yates J found that there was a divergence in opinion on switching patients to aripiprazole, in particular, to treat ongoing cognitive symptoms.¹²¹ However, testimony from two witnesses detailed several incidences where the witnesses had switched patients to aripiprazole in circumstances that, if the generic company's aripiprazole was supplied, would have been infringing.¹²² More broadly, from these testimonies, Yates J drew the conclusion that their treatment strategies were representative of the practice of a 'not insignificant number of other clinicians in

110 Ibid.

111 Ibid [40].

112 Ibid [41].

113 Ibid [42].

114 Ibid [29].

115 Ibid [31].

116 Ibid [40], [43].

117 Ibid [45]–[51].

118 Ibid [56].

119 Ibid [98], [157]–[158], [179]–[181].

120 Ibid [180].

121 Ibid [204]–[243].

122 Ibid [215]–[225], [244].

Australia'.¹²³ Accordingly, if the relevant claim was valid, his Honour found that the generic company would have reason to believe that if its generic aripiprazole was supplied in Australia, it would be put to the infringing use.¹²⁴

From this analysis on the current state of play of s 117(2)(b), a few conclusions can be drawn. From *AstraZeneca* it can be observed that in circumstances where doctors use medical knowledge to prescribe drugs, and pricing mechanisms incentivise doctors to prescribe (or pharmacists to dispense) off-label use of drugs with pill splitting, s 117(2)(b) supply infringement can be established. Similarly, *Otsuka* indicates that if a drug is patented for treatment of a disease in certain scenarios, and doctors are likely to prescribe the drug in those scenarios, then infringement under s 117(2)(b) may arise. The High Court reasoning in *Sanofi* means it is more difficult for patent holders to prove s 117(2)(b) actions in circumstances of multiple ARTG listings, or where instructions are given to medical professionals to not prescribe a drug for certain uses. However, if good evidence of infringement can be adduced, such as that observed in *Lambert*, the hurdle created by *Sanofi* may be overcome and the *requisite reason to believe* established.

B Reluctance Realised

The analysis below offers an historical legal context to the state of play described above, and assists in illustrating the manifestations of Monotti's first two reasons for reluctance. Whilst this background is not vital to understanding the problems that s 117 creates, it is necessary to understand them in detail, and to lay the proper framework for any reform. As a reminder, the three reasons outlined by Monotti were that:

1. the operation of the provision 'converts the sale of an unpatented product into an infringement of a process claim';¹²⁵
2. supply infringement 'enables and encourages patent misuse and tying of the supply of unpatented products to the supply of patented products';¹²⁶ and
3. supply infringement creates a further supplementary right for the patent holder to sue under (in addition to other causes of action for infringement).¹²⁷

The *Patents in Australia Report* leading to the *Patents Act* did not consider that patent misuse affected the 'general thrust' of their recommendation to implement supply infringement.¹²⁸ However, as described below, when Monotti's first and second reasons for reluctance are analysed in terms of the current operation of s 117(2)(b), a type of legislatively endorsed patent misuse does appear to be

123 Ibid [245].

124 Ibid [247].

125 Monotti, 'Contributory Infringement of a Process Patent', above n 9, 220–1.

126 Ibid.

127 Ibid.

128 *Patents in Australia Report*, above n 18, 67.

affecting the operation of the provision and extending patent rights into areas that should be open to competition. The third reason for reluctance — supplementary causes of action — is addressed in pt III.

As articulated by Monotti,¹²⁹ underpinning the first reason for reluctance is Dixon J's famous statement that 'whatever is not included in a monopoly granted is *publici juris* and may be freely used as of common right'.¹³⁰ Or in modern economic terms, patent rights are the exception to free market trade.¹³¹ However, as also pointed out by Monotti with regards to this first reason:

justification for permitting a limited extension of such a monopoly lies in seeing the supply of the product for use in a patented process as akin to stealing the benefits of the discovery of a hitherto unknown property of that product. Other justifications for an extension of the patent monopoly to prevent this type of behaviour include the need to stimulate invention and the need to ensure that the endeavours and investments of the inventor do not go unrewarded. To refuse to protect against contributory infringement would give incentive to those who wait for the inventions of others rather than encouraging them to take the initiative.¹³²

Circumstances supporting this justification were present in the famous US case, *Dawson Chemical Co v Rohm & Haas Co* ('*Dawson Chemical*').¹³³ This case is regularly cited as supporting supply infringement legislation, and has been influential in Australia.¹³⁴ In *Dawson Chemical* the relevant patent claimed a use of propanil for inhibiting growth of weeds in rice crops.¹³⁵ Prior to the patent application, propanil was a known chemical; accordingly, the patentee could only claim its new method of use in rice crops.¹³⁶ If supply infringement was not available to the patentee, no clear remedy would have been available and other companies would be able to free ride on their invention.¹³⁷ While this justification initially appears reasonable, when the operation of s 117(2)(b) is considered alongside patent misuse, cracks appear in its operation.

Monotti's second reason, patent misuse and tying, does not have a rich history in Australia or the UK, but does in the US, and is highly relevant to the current operation of s 117(2)(b). Indeed, indirect infringement case law history in the

129 Monotti, 'Contributory Infringement of a Process Patent', above n 9, 220.

130 *Walker v Alemite Co* (1933) 49 CLR 643, 658.

131 *Patents in Australia Report*, above n 18, 11–18; Economic Planning Advisory Council, *Promoting Competition in Australia* (Australian Government Publishing Service, 1989) 5–6; Philip L Williams, 'Why Regulate for Competition?' in Michael James (ed), *Regulating for Competition?* (The Centre for Independent Studies Ltd, 1989) 13, 13–16.

132 Monotti, 'Contributory Infringement of a Process Patent', above n 9, 220.

133 448 US 176 (1980).

134 See Monotti, 'Contributory Infringement of a Process Patent', above n 9, 219; *Monash Report*, above n 1, 254–9, 276; *Sanofi* (2013) 304 ALR 1, 76 [301] (Crennan and Kiefel JJ); *Collins* (2008) 235 CLR 619, 644–6 [106]–[113] (Crennan J). See generally Monotti, 'Infringement of a Patent by Authorisation', above n 16, 7; *Patents in Australia Report*, above n 18, 66–7.

135 *Dawson Chemical* 448 US 176, 183 (1980).

136 *Ibid.*

137 Monotti, 'Contributory Infringement of a Process Patent', above n 9, 219–21.

US is the equivalent of the British Library — its collection is vast. As such, a brief interlude into the intricacies of US law is needed to properly understand why there was reluctance to enact equivalent legislation in Australia. Prior to the *Patents in Australia Report*, the Committee sought expert advice on a variety of areas and commissioned Monash University to report on a number of issues.¹³⁸ The *Monash Report* was quite thorough in its treatment of supply infringement, addressing both the issue and indirect infringement more generally in over 70 pages.¹³⁹ Importantly, the *Monash Report* also canvassed the related issue of supply infringement and patent misuse in the US.¹⁴⁰ Thus, the *Monash Report* provides Australia's most comprehensive assessment of patent misuse. The analysis presented below builds on that assessment.

The *Monash Report* described the 1912 Supreme Court decision of *AB Dick v Henry* (*AB Dick*),¹⁴¹ as the 'high water mark' of common law 'contributory infringement' in the US.¹⁴² In *AB Dick*, the plaintiff sold a rotary mimeograph, a type of low-cost printing press that operated with a stencil attached to a tumbler laden with ink. Its function was to roll over paper pressing out text.¹⁴³ The mimeograph was sold with a licence restriction that it only be used with paper, ink and other supplies made by the plaintiff.¹⁴⁴ The defendant sold ink that was not supplied by the plaintiff, but was suitable for use with the mimeograph, with knowledge of the licence restriction and with an expectation that the ink would be used with the mimeograph.¹⁴⁵ The plaintiff argued that the defendant's conduct constituted contributory infringement. The majority found that any (legal) contractual rights could be attached to the sale of patented products and enforced as patent rights.¹⁴⁶ The majority reasoned that if a patent holder can withhold use of the patented technology completely, then it could also allow use with any conditions it desired.¹⁴⁷ At the time of this case in the US, liability for contributory infringement was satisfied if a third party was found to have an intention of assisting a person to infringe a patent.¹⁴⁸ As a result, offering to supply ink with knowledge that it would be used with the mimeograph was sufficient to satisfy these tests.¹⁴⁹

138 *Monash Report*, above n 1, iii.

139 *Ibid* 209–79.

140 *Ibid*. See generally Giles S Rich, 'Infringement Under Section 271 of the Patent Act of 1952' (1953) 35 *Journal of the Patent Office Society* 476.

141 224 US 1 (1912).

142 *Monash Report*, above n 1, 231–2. The term contributory infringement is used here because that was the cause of action in the case. There is a difference between common law contributory infringement in the US and s 117 supply infringement. However, for the purposes of illustrating patent misuse, it is not necessary to explore these differences.

143 *AB Dick*, 224 US 1, 11 (1912).

144 *Ibid* 25–6.

145 *Ibid* 11–12.

146 *Ibid* 14–48. See especially 24–5.

147 *Ibid* 28–32.

148 *Ibid* 33–5.

149 *Ibid* 48–9.

The majority's position in *AB Dick* led to a proliferation of cases in which a patent holder relied on licence restrictions to tie-in non-patented products.¹⁵⁰ The phrase 'tie-in' refers to the practice of selling one product and including another product as an obligatory part of the sale. However, opposition arose to this practice.¹⁵¹ Within a few years, the case of *Motion Picture Patents Co v Universal Film Manufacturing Co* ('*Motion Picture Patents*')¹⁵² was decided in the Supreme Court. The issues were 'virtually identical' to *AB Dick*,¹⁵³ but the law and jurisprudence had developed in between times. The majority in *Motion Picture Patents* expressly overruled *AB Dick*.¹⁵⁴ The Court stated that:

every patent must be limited to the invention described in the claims of the patent, and that it is not competent for the owner of a patent, by notice attached to its machine, to in effect extend the scope of its patent monopoly by restricting the use of it to materials necessary in its operation ...¹⁵⁵

Arguments against using 'contributory infringement' to restrain supply of goods for use with the patented invention became known as 'patent misuse'.¹⁵⁶ In this context, patent misuse became a general defence based on patent holders improperly extending patent rights into uses that did not actually infringe patent claims. As described in the *Monash Report*:

opposition [to *AB Dick*] led to the emergence of the equitable doctrine of patent misuse which has been likened to the equitable doctrine of clean hands in that it prevents a patentee from obtaining relief in respect of infringement if the infringer is able to establish that the patentee has engaged in improper practices. To begin with, patent misuse was used in cases where the patentee brought an infringement action against a contributory infringer who had supplied goods or materials to a person who was using the patented invention under licence from the patentee.¹⁵⁷

Reliance on the patent misuse doctrine continued to increase. As described by Roger Hodgeman, the application of patent misuse in the subsequent Supreme Court cases of *Mercoid Corp v Mid-Continent Investment Co*,¹⁵⁸ and *Mercoid Corp v Minneapolis-Honeywell Regulator Co*,¹⁵⁹ led some lower courts to conclude that supply infringement effectively no longer existed.¹⁶⁰ This meant that in the 32 years between *AB Dick* and the two *Mercoid* cases, supply infringement went

150 *Monash Report*, above n 1, 233. See generally Roger B Hodgeman, 'Resolution of the Conflict Between Contributory Infringement and Patent Misuse: Dawson Chemical Co v Rohm & Haas Co' (1981) 50 *University of Cincinnati Law Review* 314, 318–19.

151 *Monash Report*, above n 1, 233.

152 243 US 502 (1917).

153 *Monash Report*, above n 1, 234.

154 *Motion Picture Patents*, 243 US 502, 516 (1917).

155 *Ibid* 516.

156 *Monash Report*, above n 1, 233–4.

157 *Ibid*.

158 320 US 661 (1944).

159 320 US 680 (1944).

160 Hodgeman, above n 150, 323–4; Rich, above n 140, 490; *Monash Report*, above n 1, 240–1.

from expanding to protect tie-ins as patent rights, to not being recognised at all. In 1952, legislation was specifically drafted in the US to address patent misuse and indirect infringement.¹⁶¹ Referring to the US cases discussed above, Giles Rich, one of the drafters of the amending § 271 legislation and later a Federal Circuit judge, stated that the common law ‘experiment’ with contributory infringement had ‘not worked out very well’.¹⁶²

To date, Australia has not experienced the same vicissitudes with supply infringement and patent misuse. This is probably in large part due to the fact that since 1909, Australian patent law has had provisions analogous to the current s 144 that generally prohibit tie-ins.¹⁶³ However, these provisions have only limited the extension of patent rights in the circumstances of contractual tie-ins.¹⁶⁴

As described above, in Australia, the facts of *Dawson Chemical* have consistently been used to illustrate why supply infringement should be legislated in Australia.¹⁶⁵ There is no doubt it is a landmark case, particularly in the US, because it is seen as balancing supply infringement and patent misuse.¹⁶⁶ However, ironically, issues relating to infringement were not the central issue in the case. It was conceded by the defendant that if patent misuse was not found, then it had infringed the patent by supplying propanil.¹⁶⁷ The primary issue was whether the defence of patent misuse applied, given that since 1952, patent misuse had been modified by the operation of 35 USC § 271(d).

In Roger Hodgeman’s analysis of *Dawson Chemical* he commented that:

It is arguably improper to call [the patentee’s] control of propanil a ‘monopoly’. ‘Monopoly’ connotes the exclusive commercial control of a thing that the public freely enjoyed prior to the existence of control. Because it was unpatented, propanil was ‘freely enjoyed’ by the public prior to [the patentee’s] procurement of the Wilson patent. Realistically, however, propanil was worthless and could not be ‘enjoyed,’ freely or otherwise, because it had no practical use. Propanil was merely a known

161 35 USC § 271.

162 Rich, above n 140, 476. See also Giles S Rich, ‘Congressional Intent — Or, Who Wrote The Patent Act of 1952?’ in *Patent Procurement and Exploitation: Protecting Intellectual Rights* (Southwestern Legal Foundation, 1963) 61–78.

163 *Patents Act 1903* (Cth) s 87B, as amended by *Patents Act 1909* (Cth) s 15; *Patents Act 1990* (Cth) s 144. See also Charles Lawson, ‘Tie-ins in the Patents Act 1990 (Cth), s 144: Perhaps it’s Time to Modernise?’ (2010) 21 *Australian Intellectual Property Journal* 202, 203–4.

164 For example, in *National Phonograph Company of Australia Ltd v Menck* (1911) 12 CLR 15, the Privy Council upheld the right of a patentee to impose restrictions on the resale price of a patented product provided adequate notice was given. See generally Peter Heerey and Nicole Malone, ‘RPM for RPM: National Phonograph Company of Australia v Menck’ in Andrew T Keyon, Megan Richardson and Sam Ricketson (eds), *Landmarks in Australian Intellectual Property Law* (Cambridge University Press, 2009) 37.

165 See Monotti, ‘Contributory Infringement of a Process Patent’, above n 9, 219; *Monash Report*, above n 1, 254–9, 276; *Sanofi* (2013) 304 ALR 1, 76 [301] (Crennan and Kiefel JJ); *Collins* (2008) 235 CLR 619, 644–6 [106]–[113] (Crennan J). See generally Monotti, ‘Infringement of a Patent by Authorisation’, above n 16, 7; *Patents in Australia Report*, above n 18, 66–7.

166 See generally Hodgeman, above n 150, 338–40.

167 *Dawson Chemical* 448 US 176, 185–6 (1980).

chemical compound catalogued in scientific journals, waiting for someone to discover a valuable use for it. Thus [the patentee] did not truly take something from the public domain in the ‘monopoly’ sense.¹⁶⁸

Hodgeman went on to state:

When a person discovers a use for a known chemical compound, and the compound is a material part of a new process and a nonstaple with no substantial noninfringing use, it is justified to grant the inventor of the process the right to exclude all others from the sale of the chemical compound. This right is a logical compromise between the strict view that all monopolies are evil, and the argument that it is impracticable to sue widely scattered, individual, [infringers who exploited] the process patent.¹⁶⁹

While Hodgeman was generally praising the balance struck in the drafting of 35 USC § 271(c)–(d) and the Supreme Court’s approach in *Dawson Chemical*, when this analysis is turned to s 117(2)(b), the same compromise does not appear to be reached. The current operation of s 117(2)(b) means that for products without a variety of uses, a patent can be used to gain a monopoly over the entire trade of the product and foreclose the market, as long as a supplier has reason to believe a person will put the product to an infringing use. Indeed, if these requirements are met, it can effectively create a legislative form of patent misuse without tying, and ‘evergreen’ some inventions, as it provides manufacturers with patent protection for new, related uses for known pharmaceutical compounds and thereby allows them to continue to control the market for the product.¹⁷⁰ Such outcomes are most vividly demonstrated in the fact scenarios of *Otsuka* and *AstraZeneca*, if it is assumed that the patents were valid.

The patent holders in *Otsuka* had previously controlled patent rights to aripiprazole as a chemical, that is, per se rights that entitled them to control markets for the chemical in other jurisdictions. However, relevant patent applications had never been made in Australia, and at the time of the case these patents had expired.¹⁷¹

168 Hodgeman, above n 150, 340.

169 Ibid.

170 This line of reasoning has emerged in the US, albeit via a slightly different infringement mechanism. The US case of *AstraZeneca Pharmaceuticals LP v Apotex Corp*, 669 F 3d 1370 (Fed Cir, 2012) (*‘AstraZeneca LP’*) is homologous to *AstraZeneca*, with the use of rosuvastatin as a central issue. In *AstraZeneca LP*, the patent rights holder alleged that a generic company would infringe § 271(e)(2). This provision deems that applying for approval of certain types of pharmaceuticals, or uses of pharmaceuticals when protected by patent, constitutes infringement. The patent holders alleged infringement ‘because even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available’: at 19. The Federal Circuit unanimously found the argument ‘unpersuasive’ for two reasons. First, statements required for government approval under 21 USC 355(j) and labelling requirements are designed to ‘carve out patented indications’ that are non-infringing. Secondly, if the patent holders’ argument were to succeed it ‘would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound ... Generic manufacturers would effectively be barred altogether from entering the market’: at 19–20.

171 *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* (2012) 291 ALR 763, 765, 789. See US Patent 5,006,528 and European Patent 367, 141.

Although the patent holders had no right to per se protection in Australia,¹⁷² the injunction that operated between the interlocutory hearings and the trial decision had the same effect in that the respondent was enjoined from supplying aripiprazole for any purpose.¹⁷³ Since aripiprazole is recommended for first- and second-line treatment of schizophrenia,¹⁷⁴ this injunction travels beyond the patent claim for treatment-resistant schizophrenia or chronic schizophrenia in circumstances where a patient has failed to respond to two or more other drugs. The respondents did contest the breadth of the interlocutory injunction, arguing it should be limited to the infringing use, but were not successful.¹⁷⁵

With regards to rosuvastatin in *AstraZeneca*, per se rights to the chemical do currently exist,¹⁷⁶ but not in Australia.¹⁷⁷ If infringement was ultimately found and a permanent injunction awarded, then the injunction may have operated as per se protection — as it did between the interlocutory hearing and trial judgment.¹⁷⁸ In terms of the effect on the market for rosuvastatin, testimony at first instance in *AstraZeneca* described the asserted patented uses of rosuvastatin as less common than the non-patented uses.¹⁷⁹ This means that if the patentees had been successful, they would have the exclusive rights to at least twice as many uses of rosuvastatin than their patent actually claimed.

Compared to propanil in *Dawson Chemical*, which, prior to the patent, had almost no value to the community, rosuvastatin and aripiprazole had significant value prior to the patents in their respective cases. While figures on patented and non-patented uses of aripiprazole and rosuvastatin are not available, data is available on the annual government and public spending in certain years. In 2011, the Australian Government and patients together spent over \$32 million on aripiprazole.¹⁸⁰ In 2013, the government and patients spent over \$418 million on rosuvastatin.¹⁸¹ As a result, the consequences of injunctions granted via s 117(2)(b) that foreclose markets for these pharmaceuticals, whether permanent or interlocutory, are substantial.

It should be noted that in obiter the Full Federal Court in *AstraZeneca* did raise the possibility that injunctive relief may be narrowed, or not granted at all.¹⁸² This is an interesting development by the Court and builds on its concern about

172 See US Patent 5,006,528 and European Patent 367, 141.

173 *Generic Health* (2013) 296 ALR 50, 60–1 [40]–[44] (Emmett J), 78 [130]–[131] (Bennett J), 94–5 [262]–[263] (Greenwood J).

174 *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* (2012) 291 ALR 763, 768–9 [37].

175 *Generic Health* (2013) 296 ALR 50, 60–1 [40]–[44] (Emmett J), 78 [130]–[131] (Bennett J), 94–5 [262]–[263] (Greenwood J).

176 See US Patent RE37, 314.

177 *Apotex* (2013) 100 IPR 285, 289 [3].

178 *Apotex Pty Ltd v AstraZeneca AB [No 2]* [2012] FCA 142 (28 February 2012) [2], [28], [46].

179 *Apotex* (2013) 100 IPR 285, 408–9 [502].

180 Department of Health, *Australian Statistics on Medicine 2011* (2013) 158 <<http://www.pbs.gov.au/statistics/asm/2011/australian-statistics-on-medicines-2011.pdf>>.

181 Department of Health, *Expenditure and Prescription Twelve Months to 30 June 2013* (2013) 11 <<http://www.pbs.gov.au/statistics/2012-2013-files/expenditure-and-prescriptions-12-months-to-30-06-2013.pdf>>.

182 *AstraZeneca* (2014) 226 FCR 324, 420–1 [442]–[444].

extending patent rights beyond the bounds of claims.¹⁸³ Whether this is an appropriate response is addressed in more detail below.

IV SUPPLEMENTARY INFRINGEMENT ACTIONS

A Background

In legislating supply infringement it was always known that if liability was found then two parties could be liable for infringement: infringers by exploitation and suppliers. However, the basis for its inclusion was that it would create a ‘more effective, realistic and just’ enforcement system.¹⁸⁴ More specifically, it would enable efficient enforcement of patent rights against suppliers who facilitate and are ‘responsible’ for infringement.¹⁸⁵

When Monotti described her third reason for reluctance, she did so by addressing infringement by exploitation.¹⁸⁶ Whilst this is clearly a relevant consideration, in the pharmaceutical scenario, it is not the only type of infringement. In addition to infringement by exploitation and supply infringement under s 117, there are currently three other types of infringement. These are authorisation,¹⁸⁷ which is stipulated in s 13(1) of the *Patents Act*, as well as common design,¹⁸⁸ and procurement,¹⁸⁹ both of which have been developed through case law. All three causes of action can be argued alongside s 117 to create liability for suppliers. However, the relevance of these causes of action in this article is not that they could also create infringement liability for generic drug companies, but that they may create liability when doctors prescribe, or pharmacists dispense, drugs for patented secondary medical indications. It is argued here that all three causes of action arguably create liability for doctors or pharmacists.

Common design requires at least ‘two persons who agree on common action in the course of and to further which one of them commits’ infringing actions.¹⁹⁰ However, it is not enough that ‘two or more persons assisted or concurred’ in infringement: ‘some common design is necessary’.¹⁹¹ In *AstraZeneca*, testimony

183 Ibid 420 [440]–[441].

184 *Patents in Australia Report*, above n 18, 67.

185 Ibid.

186 Monotti, ‘Contributory Infringement of a Process Patent’, above n 9, 221.

187 *Patents Act* s 13(1). For a review and critique in regard to s 117, see Monotti, ‘Contributory Infringement of a Process Patent’, above n 9.

188 *Apotex Pty Ltd v Les Laboratoires Servier (No 2)* (2012) 293 ALR 272, [22]–[26]; *Morton-Norwich Products v Intercen Ltd* [1978] RPC 501, 512–6; *Bayer Pharma Aktiengesellschaft v Genentech Inc* (2012) 98 IPR 424, 428–32 [23]–[38]; *SNF* (2011) 92 IPR 46, 115–6 [310]–[313].

189 *Collins* (2008) 235 CLR 619, 643 [102] (Crennan J); *Ramset* (1999) 164 ALR 239, 258–9 [41]; *Danisco AS v Novozymes AS (No 2)* (2011) 91 IPR 209, 244–6 [159]–[167].

190 *Morton-Norwich Products Inc v Intercen Ltd* [1978] RPC 501, 512 (Graham J), affd in *BEST Australia Ltd v Aquagas Market Pty Ltd* (1988) 83 ALR 217, 220–1; *Murex Diagnostics Australia Pty Ltd v Chiron Corp* (1995) 55 FCR 194, 206; *Apotex Pty Ltd v Les Laboratoires Servier (No 2)* (2012) 293 ALR 272, 277–8 [22]–[26].

191 *WEA International Inc v Hanimex Corporation Ltd* (1987) 17 FCR 274, 283 (Gummow J).

from medical doctors indicated that they ‘regularly’ agreed to requests from patients to prescribe higher dosages of drugs to permit them to engage in tablet splitting.¹⁹² In such a situation, there is clearly an agreement between the parties on a course of action. As such, the doctor is doing more than simply assisting, since without their assistance the infringement cannot occur. Although more evidence would be needed to succeed in a common design case, this evidence certainly forms a basis for such an action.

The current orthodox conception of authorisation emerges from s 13(1) of the *Patents Act*, and is augmented by analogy to copyright. To be liable for authorisation a party must have ‘sanctioned, approved and countenanced’ infringement,¹⁹³ however, liability will only be found when all the facts of the case are considered.¹⁹⁴ In *SNF*,¹⁹⁵ Kenny J found authorised infringement when a party supplied a key component of a method patent, advised how to conduct infringing actions, and had the power to prevent infringement because they could choose not to supply the component.¹⁹⁶ On the question of the required mental state, Kenny J stated that it is immaterial whether an authoriser knows that actions would result in infringement.¹⁹⁷ In *Roadshow Films Pty Ltd v iiNet Ltd*,¹⁹⁸ the High Court unanimously held that an internet service provider (‘ISP’) did not authorise the copyright infringement of its customers when they downloaded infringing content.¹⁹⁹ In reaching this conclusion the Court put significant weight on the fact that the only power the ISP had to prevent their client’s infringement was by terminating the internet services they provided.²⁰⁰ A power that would not prevent infringement, but would simply prevent further infringement via that ISP as an intermediary.²⁰¹ Consequently, in a scenario of a doctor writing a script and instructing a patient how to use a drug for an infringing use, by analogy there appears to be a good argument that the doctor (or the pharmacist in similar circumstances of dispensation) could be liable for authorised infringement. Indeed, by refraining to offer such advice they would avoid infringement and the patient would also receive the same treatment, albeit at a higher cost. As a result, it seems there is a reasonably strong argument that doctors, or pharmacists, could be found liable for authorised infringement if they advise patients to use drugs for infringing purposes.

192 *AstraZeneca* (2014) 226 FCR 324, 419 [436].

193 *SNF* (2011) 92 IPR 46, 119 [325]; *Roadshow Films Pty Ltd v iiNet Ltd* (2012) 248 CLR 42, 60–3 [43]–[51] (French CJ, Crennan and Kiefel JJ), 83–6 [121]–[130] (Gummow and Hayne JJ). However, it should also be noted that this approach has been criticised for ignoring the legislating history of the *Patents Act*.

194 *Roadshow Films Pty Ltd v iiNet Ltd* (2012) 248 CLR 42, 48 [5] (French CJ, Crennan and Kiefel JJ).

195 *SNF* (2011) 92 IPR 46.

196 *Ibid* 118–19 [322]–[327]. This case was appealed, but only on invalidity, not infringement: see *SNF (Aust) Pty Ltd v Ciba Specialty Chemicals Water Treatments Ltd* (2012) 96 IPR 365, 365–6.

197 *SNF* (2011) 92 IPR 46, 119 [325].

198 (2012) 248 CLR 42.

199 *Ibid* 69–71 [71]–[78] (French CJ, Crennan and Kiefel JJ), 87–9 [136]–[143] (Gummow and Hayne JJ).

200 *Ibid* 69 [70] (French CJ, Crennan and Kiefel JJ), 88 [139] (Gummow and Hayne JJ).

201 *Ibid* 88 [139] (Gummow and Hayne JJ).

With regard to procured infringement, in the Full Federal Court decision of *Ramset*,²⁰² Burchett, Sackville and Lehane JJ, in a joint judgment, became the first Australian court to find procured infringement in Australia. The defendant in *Ramset* was found to have infringed the plaintiff's apparatus patent by providing parts, but not the whole combination, of the patented apparatus.²⁰³ The Court found that the parts combined with instructions, the circumstances of sales and the way in which the parts were to be used, gave rise to common law procurement liability.²⁰⁴ After extensively reviewing authorities on procured infringement, Burchett, Lehane and Sackville JJ stated that:

liability for infringement may be established, in some circumstances, against a defendant who has not supplied a whole combination (in the case of a combination patent) or performed the relevant operation (in the case of a method patent). The necessary circumstances have been variously described: the defendant may 'have made himself a party to the act of infringement'; or participated in it; or procured it; or persuaded another to infringe; or joined in a common design to do acts which in truth infringe. All these go beyond mere facilitation. They involve the taking of some step designed to produce the infringement, although further action by another or others is also required. Where a vendor sets out to make a profit by the supply of that which is patented, but omitting some link the customer can easily furnish, particularly if the customer is actually told how to furnish it and how to use the product in accordance with the patent, the court may find the vendor has 'made himself a party to the [ultimate] act of infringement'. He has indeed procured it. So to hold is not in any way to trespass against the established line of authority which, as Dixon J made clear in *Walker v Alemite*, is based upon the need to confine a monopoly to the precise area in which it operates. That protects the mere vendor of an old product, though selling with knowledge of the purchaser's intention to infringe a combination patent; but it affords no excuse to the person who sets out to induce customers to do what falls fairly within the area of the monopoly.²⁰⁵

It should also be noted that their Honours distinguished their finding of procured infringement from common design infringement, holding that, when a party procures another to infringe a patent, there is no need to prove that there was a common design between the parties.²⁰⁶

Anecdotally, the author is aware of doctors who have knowingly advised patients to split pills to avoid purchasing more expensive patent protected versions. Indeed, the author has specifically been advised to do it. In reference to the procurement test articulated in *Ramset*, there is probably a good argument that doctors or pharmacists who prescribe/dispense drugs, and advise how to use

202 *Ramset* (1999) 164 ALR 239.

203 *Ibid* 263 [54].

204 *Ibid* 258–9 [41]–[42].

205 *Ibid* 258–9 [41].

206 *Ibid* 263 [53]–[54].

them for infringing purposes, have taken ‘some step designed to produce the infringement, although further action by another or others is also required’.²⁰⁷

B Reluctance Realised

Assuming that doctors and pharmacists in some circumstances are liable for patent infringement, a curious situation may arise where four parties in the medical chain may be liable for patent infringement: doctors, pharmacists, patients and generic companies. This scenario is particularly interesting when it is likely that doctors and pharmacists are the parties that take deliberate steps towards specific infringing actions, but generic companies may be actively trying to avoid it. In *Otsuka, AstraZeneca* and *Lambert* the generic companies proposed sending letters to doctors and pharmacists instructing them not to issue their drug for infringing purposes.²⁰⁸ If there was no chance that doctors would prescribe drugs for patented secondary medical indications (or that pharmacists would dispense them), then the liability of generic companies would never arise. Nevertheless, it is the generic parties that are currently in court defending actions for supply infringement.

It should be made clear that pursuing doctors, pharmacists, or patients for patent infringement is not being advocated. However, in reference to the government’s justifications for legislating supply infringement, in the context of using generic drugs for patented secondary medical indications, it does appear that in some instances generic companies may have a low level of responsibility and be playing a remote role in facilitating infringement. It is quite possible that in many scenarios doctors and pharmacists are liable for procured infringement or authorised infringement, and possibly more culpable for the infringement by exploitation that is committed by patients. As a result, in these circumstances, s 117(2)(b) appears to be extending liability too far.

V BRIEF COMMENTS ON SOLUTIONS

Although the focus of this article is to outline problems with the current operation of s 117(2)(b), it would be remiss not to comment on possible solutions. Admittedly, a variety of legislative solutions to s 117 could be formulated, but two are pertinent based on the commentary offered in this article. First, the recently released Australian Pharmaceutical Patents Review (‘PPR’) recommended that a pharmaceutical ‘carve out’ be introduced into s 117.²⁰⁹ Second, as hinted in the extracts from Hodgeman, the analogous US provision to s 117(2)(b), § 271(c),

207 Ibid 258 [41]. Subsequently approved of in obiter in *Collins v Northern Territory* (2007) 161 FCR 549, 562 [29] (French J).

208 *Generic Health* (2013) 296 ALR 50, 60–1 [40]; *Apotex* (2013) 100 IPR 285, 411 [512]; *Warner-Lambert Co LLC v Apotex Pty Ltd* (2014) 106 IPR 59, 62 [12], 69–73 [52], 79–80 [72]–[74].

209 Australian Government, *Pharmaceutical Patents Review* (2013) 140.

excludes liability for supply of products that have substantial non-infringing uses.²¹⁰

In reference to the ‘carve out’ it is useful to refer to the PPR recommendation in full:

Section 117 of the Patents Act should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. The law should establish a presumption that ‘reasonable steps’ have been taken where the product has been labelled with indications which do not include any infringing indications.²¹¹

Whilst this recommendation has merit, if it is to be implemented various issues will need to be worked through. A non-exhaustive list of issues includes whether the reasonable steps provision is to be implemented into s 117 or specifically into s 117(2)(b) (from the PPR this is not clear), and whether ‘reasonable steps’ should apply solely to pharmaceutical patents or all patents. Moreover, the ‘carve out’ will not address issues of doctors’ or pharmacists’ liability under procurement or authorisation. Nor will it prohibit patients taking generic drugs for patented purposes, because this often occurs without doctors or pharmacists looking at labels for drugs. Consequently, whilst the ‘carve-out’ will remove liability for generic companies, it does not solve the infringement at issue in *AstraZeneca, Otsuka or Lambert*.

With regard to the US approach of excluding products from supply infringement liability that have substantial non-infringing uses, the US Federal Circuit Court of Appeals has stated ‘that non-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.’²¹² However, this exemption is problematic. Similar to the ‘carve out’, it does not address the issue of doctors’ or pharmacists’ liability, or the infringement by exploitation complained of. That aside, the exemption may be too broad, resulting in insufficient protection for originator pharmaceutical companies. In at least two of the key cases discussed, the non-infringing uses of aripiprazole, and rosuvastatin would likely be classified as substantial for the purposes of the exemption. As a result, a scenario may arise where the infringement liability offered under the *Patents Act* does not sufficiently incentivise development of secondary medical indications because the exclusive rights do not encompass any type of infringement by generic companies under s 117(2)(b). Indeed, this lack of protection argument has also been directed towards pharmaceutical carve outs, where anecdotal evidence suggests that the lack of protection directs research

210 35 USC § 271(c).

211 PPR, above n 209, 140.

212 *Vita-Mix Corp v Basic Holding Inc* 581 F 3d 1317, 1327 (Fed Cir, 2009).

and development away from pharmaceuticals that already have established safety profiles.²¹³

The possible refusal of injunctions, as mooted by the unanimous Full Court bench in *AstraZeneca*, is an interesting development in Australian patent law and intellectual property law more broadly. It is sometimes easy to forget, particularly in intellectual property orientated full hearings, that injunctions are equitable remedies and judges can exercise discretion when awarding them. The Full Court indicated that the breadth of injunctions may be narrowed based on the scale of infringing activity, the loss to patentees and the number of non-infringing actions.²¹⁴ However, instead of refusing injunctive relief when infringing actions are found, a more logical step may be to refine the law to ensure only infringing activity is captured, or even more preferably, prevented. As such, injunctions and other solutions discussed in this article may ultimately play a role in refining the law. However, other solutions could be fashioned and it appears that further researched is warranted.

Returning again to the original justifications for implementing s 117, they were: that it would create a ‘more effective, realistic and just’²¹⁵ enforcement system, promote international harmonisation, and remove an area of uncertainty.²¹⁶ It is beyond the scope of this work to exhaustively consider all three rationales, but where the analysis of Monotti’s reasons for reluctance is relevant to the government’s justifications, some comment should, and has been, made. The analysis in pts III and IV of this article is relevant to whether the enforcement system is ‘effective, realistic and just’, and the analysis in this part has, albeit briefly, touched on international harmonisation. Thus far this article has yet to comment on ‘certainty’.

The type of certainty the government rationale originally referred to was whether or not supply infringement existed at common law in Australia, which, at the time, was a matter open to some doubt.²¹⁷ Whilst it is now clear that supply infringement does exist, a new type of uncertainty has emerged. One of the PPR’s justifications for the pharmaceutical ‘carve out’ was that the provisions ‘are unclear and lead to uncertainty for both patentees and generic manufacturers’.²¹⁸ It is not immediately apparent what is meant by ‘uncertainty’ in the PPR, but it seems logical that it is in reference to understanding how to apply the decisions in the four key cases described in this article, and others, in formulating drug development, distribution and enforcement strategies. This is a challenge for many lawyers, and probably a source of some bemusement for pharmaceutical

213 Brian Cordery, ‘Use of Medicines for Carved Out Indications in Europe — Time for a Change in Approach?’ (2013) 19(1) *Journal of Commercial Biotechnology* 55, 57–8.

214 *AstraZeneca* (2014) 226 FCR 324, 420–1 [439]–[444]. See also, *Otsuka* [2015] FCA 634 (29 June 2015) [247].

215 *Patents in Australia Report*, above n 18, 67.

216 Minister for Science, above n 19.

217 *Ibid.* See also, Monotti, ‘Contributory Infringement of a Process Patent’, above n 9, 217–18.

218 PPR, above n 209, 138.

management personnel. Any future proposals for law reform should keep this new iteration of an old concern in mind.

VI CONCLUSION

This article demonstrates that all three of the reasons posited by Monotti as to why Australian lawmakers were reluctant to legislate supply infringement now arise under the operation of s 117(2)(b). Of particular concern is that legislation has created a type of patent misuse, allowing foreclosure of markets even though the infringing products supplied may have substantial non-infringing trade. This issue is highly relevant for pharmaceutical drugs. At a time when there is significant concern about the high costs of drugs, creating a solution to this issue could result in significant savings.²¹⁹

Ultimately, supply infringement will probably always be controversial, as it can extend patent rights beyond patent claims into areas of competitive trade and can create liability for multiple parties with different levels of culpability. On the competition point, Crennan J has stated, quoting Blackmun J from the US Supreme Court, ‘an inevitable concomitant of the right to enjoin another from contributory infringement is the capacity to suppress competition in an unpatented article’.²²⁰ Although it may be a concomitant that supply infringement suppresses competition in unpatented articles, it does not follow that Australia has struck the correct balance between protecting innovation by creating liability in various parties’ actions and limiting its suppression of competition on products that are not patented.

Various patent law reform efforts have taken place recently, but none have addressed supply infringement and other indirect forms of infringement in detail.²²¹ As explained above in pt II, the text of s 117(2)(b) was not explicitly considered by legislators prior to it being enacted. The time may be nigh for patent reform to focus in this direction.

219 Report of the National Commission of Audit, *Towards Responsible Government* (Canberra, February 2014) 95–6; Deborah Gleeson, *Cost-Cutting Crusade Ignores Health Savings* (6 March 2014) Australian Broadcasting Corporation <<http://www.abc.net.au/news/2014-02-28/gleeson-cost-cutting-crusade-ignores-vital-health-report/5289726>>.

220 *Collins* (2008) 235 CLR 619, 646, quoting *Dawson Chemical* 448 US 176, 197 (1980).

221 Various patent reforms and enquiries have recently been completed but none have thoroughly addressed indirect infringement. See generally *Intellectual Property Laws Amendment Act 2006* (Cth); *Intellectual Property Amendment (Raising the Bar) Act 2012* (Cth); Productivity Commission, *Compulsory Licensing of Patents* (2013) <<http://www.pc.gov.au/projects/inquiry/patents>>; PPR, above n 209.