

THE STATE OF THE ART DEFENCE: DEFINING THE AUSTRALIAN EXPERIENCE IN THE CONTEXT OF PHARMACEUTICALS

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One of the defences within Part 3-5 of the Australian Consumer Law is the state of the art, or development risk defence. This defence, although significant, has often been neglected in Australian jurisprudential analysis and has triggered at most generic academic analysis. However, with the rise of pharmaceutical and medical device litigation in Australia, it could become a vital weapon for Australian manufacturers against product liability claims. This paper will firstly review the two ways this defence could operate. It will also discuss the three types of defects which the defence could apply to. This paper aims to determine exactly when and how this defence should apply in Australia, in the context of pharmaceutical product liability claims.

I INTRODUCTION

Two roads diverged in a yellow wood
And sorry I could not travel both – Robert Frost.¹

These two lines from the poem “The Road Not Taken” is a perfect description of how the operation of the state of the art defence (also known as the development risk defence) has diverged into two mutually exclusive paths, with Australia as the traveller, looking down each legal path as far as it can, without making full commitment to choose one or the other.

The defence was included in the *Trade Practices Act 1974* (TPA), Part VA² which was enacted in 1992 by the *Trade Practices Amendment Act 1992* (Cth). (In 2010, the TPA regime was replaced by the *Competition and Consumer Act 2010*, which contains the Australian Consumer Law (ACL) in Schedule 2.) Controversial in nature, the defence has spawned numerous pieces of literature debating its scope, limits and benefits, as well as questioning the overall wisdom of including a defence in a purportedly strict liability regime.³ While these are all

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¹ Robert Frost, *The Road Not Taken* (undated) Poetry Foundation
<<http://www.poetryfoundation.org/poem/173536>>.

² Now known as **Part 3-5** of the *Australian Consumer Law*. Unless otherwise stated, this article will cite the provisions of the *Australian Consumer Law* in its discussion.

³ Jane Stapleton, *Product Liability* (Butterworths, 1994) 136; Jane Stapleton, ‘Liability for Drugs in the US and EU: Rhetoric and Reality’ (2007) 26 *The Review of Litigation* 991, 1005;

legitimate concerns, it appears that in Australia, the defence is here to stay. As a result, this article will not review the arguments for or against the inclusion of this defence. Rather, the aim is to deduce from the literature and overseas case law the answers to two questions for the Australian legal landscape, in the context of pharmaceutical products. The first is *when* the defence should apply. The second is *how* the defence should apply.

This paper is therefore divided into four sections. Section one will review the historical background of the defence and what limited case law there is available in Australia, to date. This exercise will reveal a rather sporadic and incomplete approach towards this defence by the Australian courts; in part possibly caused by the fact that parliament was not clear about how their objectives for the defence were to be prioritised. Section two reviews five cases from overseas jurisdictions which have either applied or considered the defence in obiter. The divide between Australian and overseas case law is sharp enough that despite Australia's tentative applications observed in section one, a definite divergence can be seen. Section three puts the two roads in context as the academic literature explains the two approaches – the narrow versus the reasonable interpretation. This evaluation lays the groundwork for section four which argues that the preferable approach is the *reasonableness* interpretation. This paper will conclude with some final recommendations which will hopefully guide future law reform initiatives.

II ON PHARMACEUTICALS

Before moving onto the defence, it is necessary to address why the topic of this paper has been limited to pharmaceutical products only. The first is the increase of pharmaceutical and medical device litigation in Australia, with *Vioxx*, *Thalidomide* and a range of allegedly faulty medical devices all making frequent appearances in the national media. This increase necessitates an examination of how the product liability regime operates with respect to such products, especially with the minimal amount of precedent in Australian case law.

Secondly, as will be discussed in a forthcoming article by the author, the inherent and unique properties of pharmaceuticals pose an equally unique challenge for legislative and regulatory controls. Indeed, upon the introduction of the product liability provisions, the then Attorney-General cautioned against too easily classifying pharmaceuticals and vaccines as defective, merely because of the existence of side effects, noting that such products “confer substantial benefits which flow to the wider community at large. The small statistical chance of injury associated with them does not of itself mean they are defective.”⁴ Such a unique product therefore warrants special analysis to ensure the law does operate as expected in these circumstances.

A *The different types of defects*

The *Explanatory Memorandum* to the Act which incorporated what is now Part 3-5 also noted the law was to operate on the basis that there were three types of

Christopher Newdick, ‘Risk, Uncertainty and Knowledge in the Development Risk Defence’ (1991) 20 *Anglo-American Law Review* 309.

⁴ Explanatory Memorandum, Trade Practices Amendment Bill 1992 (Cth), 8.

defect – design, manufacturing and instructional. *Safety defect* is defined in s9 of the ACL. Under the *Explanatory Memorandum*, the types of defects were defined as follows:

- Design defects relate to matters such as form, structure and composition of the goods. An example of a defectively designed pharmaceutical is the drug Thalidomide, where it was the inherent composition of that drug design that resulted in its teratogenic effects.
- Manufacturing defects are those related to matters such as the process of construction and assembly. An example of this is the 1937 Elixir Sulfanilamide disaster where the combination of sulfanilamide with the toxic diethylene glycol led to the deaths of over 100 people.⁵
- Instructional (warning) defects are those caused by incorrect or inadequate warnings and instructions. A general example is where a drug is designed and manufactured in accordance with manufacturer specifications, but the instructions fail to detail the side effects associated with the drug.

All these categories of ‘defect’ fall within the definition in s9. The distinction is vital to the discussion in section four, which addresses the question of *when* the defence should apply.

III SECTION ONE: THE AUSTRALIAN EXPERIENCE SO FAR

The focus of this section in terms of the policy objectives of statutory product liability regimes will be explored in detail in another article by this author and thus cannot be repeated here. Rather, this section will focus on critiquing the operation of the defence in Australia.

A *The objectives*

Based on what could be regarded as the two most important reports of the TPA reform movement in relation to product liability (the *Swanson Report*⁶ and the 1989 *Product Liability Report* from the Australian Law Reform Commission⁷ (ALRC)), it can be reasonably concluded that the regime was oriented towards consumer protection. Businesses were to be held legally and financially accountable for the products they manufactured and had quality control over.

As part of this initiative, strict liability provisions (known as warranties under the TPA) in the form of Consumer Guarantees (Part 3-2, Div 1)⁸ were introduced. Liability was imposed on the basis of what goods did (or failed to do) and the available defences did not depend on the reasonableness of the defendant’s actions. This would ensure that firstly, manufacturers would bear direct legal

⁵ Carol Ballentine, Taste of Raspberries, Taste of Death: the 1937 Elixir Sulfanilamide Incident (10 July 2010) Food and Drug Administration
<<http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/>>.

⁶ Trade Practices Act Review Committee, *Swanson Report* (1976).

⁷ Australian Law Reform Commission (ALRC), *Product Liability Report No 51* (1989).

⁸ Formerly known as “Implied Warranties” provisions in Part V, Div 2A in the *Trade Practices Act*.

responsibility for faulty goods and secondly, would ease the evidentiary burdens upon plaintiffs during litigation. Likewise, when the product liability provisions in Part 3-5 of the ACL⁹ were introduced, they were described in terms of being “strict” in liability. Little wonder therefore, that when law reform movements in the 1980s started to consider *limiting* the extent of manufacturer liability by, among other means, using the state of the art defence, there was much debate and opinion about the inclusion and operation of the defence among the legal community, consumer groups and businesses.

Yet for all the controversy it raised, Australian lawmakers appear to have had little concern about the merits of the defence when enacting it. Rather, judging from the ALRC Report in 1989¹⁰ and extrinsic materials, three considerations were sufficient to persuade them that including the defence was a good idea. The first was that ‘a number of overseas jurisdictions’ had enacted this defence in their domestic product liability legislation.¹¹ Indeed, when lawmakers enacted Part 3-5, they expressed the hope that Australians ‘should be no worse off than their European counterparts’ and ‘Australian courts would fully acquaint themselves with the emerging jurisprudence in Europe.’¹² The second was that the majority of submissions to the ALRC supported Australian lawmakers making a similar move.¹³

The third was the most sensible and that was the group of policy objectives adopted by Australian lawmakers.¹⁴ Chief among them ensuring the fair allocation of risk¹⁵ and protecting innovation.¹⁶ A manufacturer would be liable for their defective product unless ‘the existence of the defect was incapable of being ascertained by any means ... or came into existence after the product left the manufacturer’s control.’¹⁷ Where the defect was truly undiscoverable, the manufacturer was not required to pay compensation as this was not a risk they should bear.¹⁸

‘Technological and innovative development of industry’ was another policy priority.¹⁹ To impose strict liability would inhibit product innovation and deprive the community of beneficial goods as well as put Australian goods at a disadvantage in the overseas market.²⁰ In addition, from a pharmaceutical industry as well as patient well-being perspective, something was required to act as a medium between the risks of a drug which had high therapeutic value against a patient’s suffering and death due to the withholding of a drug for over-extensive testing purposes.²¹ Finally, there was concern that insurers would refuse to insure

⁹ Introduced in the form of Part VA in the *Trade Practices Act*.

¹⁰ ALRC above n 7, 47.

¹¹ Ibid.

¹² ALRC above n 7.

¹³ Ibid 48.

¹⁴ Explanatory Memorandum above n 4.

¹⁵ Ibid 49.

¹⁶ Ibid 48.

¹⁷ Ibid, 50; Trade Practices Amendment Bill 1992 (Cth); Commonwealth, *Parliamentary Debates*, Senate, 3 June 1992, 3372 (Michael Tate).

¹⁸ ALRC above n 7, 49-50.

¹⁹ Ibid 48 citing J Simpson.

²⁰ Ibid 48.

²¹ Ibid.

unforeseeable loss or injuries²²; and that costs could not be passed onto consumers, as some costs of medicines were capped.²³ On the back of these concerns, the ALRC recommended the defence be included. Manufacturers would have a continuing obligation to inform and update themselves on advances in knowledge and incorporate them into future products.²⁴

In 1992, the Senate Standing Committee was faced with the opportunity to question the inclusion of the defence. Competing submissions were placed before the Committee, which argued in support of the defence ‘that it encouraged manufacturers to test the safety of the product,’²⁵ as well as against it as it appeared to require industry to test “exhaustively” the safety of the product, which was not always possible.²⁶ Eventually the Committee decided to keep the defence on two (rather unsatisfactory) grounds: that there was no case law on the defence which could shed further light on this issue; and consequently, there was no reason to depart from the *European Product Liability Directive*.²⁷

B The law

In Australia, the defence was in s75AK(1)(c) of the TPA. When the ACL came into operation in 2011, the defence became s142(c) in Part 3-5. It states the defence is established if:

the state of scientific or technical knowledge at the time when the goods were supplied by their manufacturer was not such as to enable that safety defect to be discovered.

Two things will be noted now about the wording in the ACL, for further discussion in sections two and three. The first is that the wording substantially reflects the wording of its counterpart in s7(e) of the *European Product Liability Directive*²⁸ (the Directive). The second is that the ACL and the Directive have significantly *different* wording to the United Kingdom’s *Consumer Protection Act 1987* (CPA) and its section 4(e), which states:

the state of scientific or technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.

Despite the UK CPA having been in effect at the time this defence was passed, it may be that Australian lawmakers preferred the Directive wording, as that was the originating source of this law. As will be seen in section two however, a case

²² Ibid.

²³ Ibid.

²⁴ Explanatory Memorandum above n 4.

²⁵ Senate Standing Committee on Legal and Constitutional Affairs, Parliament of the Commonwealth of Australia, *Product Liability – Where Should the Loss Fall?* (1992) 51 citing John Goldring.

²⁶ Ibid citing Dr Ellen Beersworth.

²⁷ Ibid 52.

²⁸ Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products [1985] OJ L 210/29.

from the European Court of Justice has rendered the differences in wording of the defence a moot point.

C Defining the nature of this law

Strict liability has been defined by one leading commentator as a liability ‘which can apply to a party despite its use of all reasonable care.’²⁹ This defence does have the ability to detract the law from its strict liability nature. Kiefel J noted this discrepancy in the medical device case *Carey-Hazell v Getz Bros and Co (Australia) Pty Ltd*:

Part VA was introduced by the Trade Practices Amendment Act 1992 (Cth). The applicant submitted, in support of her contention that liability under the Part is strict, that it resulted from Report No 51, Product Liability by the Australian Law Reform Commission. The Explanatory Memorandum to the Trade Practices Amendment Bill (No 2) 1991 (Cth) does not support the applicant’s contention. It says that the purpose of the Bill is to introduce into Australia “a strict product liability regime based on the 1985 European Community Product Liability Directive ...”. It appears from what follows in the Explanatory Memorandum however that liability was to be limited by the requirement of a defect. In JD Heydon, *Trade Practices Law: Restrictive Trade Practices, Deceptive Conduct and Consumer Protection*, Lawbook Co, Sydney 2001, at [16A.80] it is observed that s75AC(1) is a departure from strict or absolute liability. The Memorandum states that the regime of strict liability provided for, when a person suffers injury as a result of a defective product, is that they have a right of compensation against the manufacturer without the need to prove negligence on the part of the manufacturer.³⁰

Whatever approach is adopted, the defence does require some reference to the manufacturer’s individual actions and comparing it against an objective standard. The liability provisions are, at best, an attempt by parliament to implement strict liability, but affected by a focus on the actions of the manufacturer due to the inclusion of the defence. At worst, it may be inferred that parliament was confused or reluctant to prioritise two equally sensitive (and potentially conflicting) objectives: compensation of injured plaintiffs as opposed to protection of business and productivity. The defence was their attempt at compromise.

D The Operation

Twenty years later, only two reported Australian cases, both heard by the Federal Court have considered this defence.

1 Contaminated oysters

The first case to consider the defence was *Ryan v Great Lakes Council*³¹ in 1999. The defendant supplier of contaminated oysters (which led to the consumers contracting Hepatitis A) was able to argue the defence successfully. Both the trial and appeal judgments considered the defence, but mostly applied it on a very *ad*

²⁹ Stapleton (1994) above n 3, 243.

³⁰ [2004] FCA 853 [182].

³¹ *Ryan v Great Lakes Council* [1999] FCA 177.

hoc basis, treating the elements of the defence as a collective group, rather than individual elements in their own right. On the facts in this case, because the testing process destroyed the oysters, tests could only be carried out on samples. As discovery of the defect and supply of the oysters were mutually exclusive, the defence applied as the defect was undiscoverable in the circumstances.³² On appeal to the Full Federal Court, the judgment also considered information derived from expert witnesses about Polymerase Chain Reaction testing, which may have enabled discovery of the contamination:

- PCR testing was a sophisticated research tool in its infancy in 1996, was available in few laboratories and was unsuitable as a test to be carried out by persons, such as oyster growers, who did not have considerable laboratory training and experience;
- PCR testing had to be performed under laboratory conditions by skilled personnel and cost between \$50 and \$200 per sample;
- There was no routine test for detecting the presence of viruses in shellfish used anywhere in the world;
- Because PCR testing gave false negatives, negative results could not be relied on, even in 1998;
- Because of the propensity of viruses to cluster together, there might be one contaminated oyster in a bed of otherwise uncontaminated ones, yet because of the tiny quantity of the virus needed to infect a consumer, that one contaminated oyster would be sufficient to cause illness;
- As at November 1996, PCR had no role to play in the routine monitoring of viral contamination of oysters;
- Reliable testing of oysters for viruses was not available in 1996;
- E coli was not an effective indication of the presence of viruses in oysters.³³

A relatively straightforward case does not need further analysis and the Court did not provide it in this instance. The closest the Court came to deconstructing the elements of the defence and questioning its scope was at [549], where his Honour Lindgren J pondered (but did not answer) just how strictly the defence itself was to be interpreted:

If the problem of ‘false negatives’ had not existed and if it had been appropriate to test by sample, an interesting question would have arisen as to whether the expression ‘such as to enable that defect to be discovered’ in s75AK(1)(c) was to be construed as importing a modifying notion of reasonableness or practicability. Let it be assumed that extrapolation from sample to bulk was valid, but that the testing of the sample had to take place at a laboratory a considerable distance from the grower’s establishment, the cost of the testing was great and the results could not be known for some days. A question would have arisen whether it could be

³² Ibid [377].

³³ *Graham Barclay Oysters Pty Ltd v Ryan, Ryan v Graham Barclay Oysters Pty Ltd; Great Lakes Council v Ryan; New South Wales v Ryan* [2000] FCA 1099.

truly said in these circumstances that the state of scientific or technical knowledge enabled the defect to be discovered.

Whether his Honour realised it or not, this question effectively goes towards the heart of the controversy in relation to this defence: how strictly or reasonably is it to be interpreted? The next and only other Australian case to have considered this defence may provide further guidance.

2 *Vioxx and Peterson*

Ten years after *Ryan*, the *Peterson Vioxx*³⁴ matter came before the Australian Federal Court, where Merck's anti-inflammatory drug Vioxx came under scrutiny. The plaintiff, Mr Peterson alleged Vioxx was associated with adverse reactions such as increasing the risk of heart attack and stroke in patients. One of the three TPA grounds raised by Peterson was that Vioxx was defective, which Jessup J agreed with, but then found the defence applied.

His Honour found that given the state of knowledge at the relevant time, the defendants had acted reasonably. His Honour outlined the adverse reaction findings of Vioxx in chronological order. For the purposes of determining whether the defence should have applied, the relevant time period was prior to September 2004.³⁵ At that time, while the data presented as evidence was sufficient to give rise to concern in the minds of doctors that Vioxx could be associated with such side effects, they were not sufficient to be regarded as scientific knowledge. A hypothesis that Vioxx had certain side effects did not amount 'to the level of scientific knowledge required to enable a defect to be discovered during the relevant period.'³⁶ At the most, his Honour was only willing to accept the applicant's alternative argument that efficacy trial results comparing Vioxx with other similar pharmaceutical drugs suggested it posed a 'worrisome and important signal of potential cardiovascular risk.'³⁷ In light of such uncertainty, Jessup J held that Merck had acted "reasonably".³⁸ The defect was one which could not be reasonably discovered and the defence should be available, despite the fact that there was enough suspicion to warrant a warning of the side effect.³⁹ This was affirmed on appeal by the Full Federal Court,⁴⁰ where it was added that in interpreting the defence, the state of scientific knowledge 'was not just the results of the [adverse reaction] study but the conclusions to be drawn from it.'⁴¹ At first instance therefore, the Federal Court appeared to accept the defence was to be interpreted on a reasonable footing, taking into account mitigating factors such as practicality and industry realities.

Secondly, his Honour identified an issue which has been consistently overlooked by Australian courts: that "defect" operates on the understanding that there are

³⁴ *Peterson v Merck Sharpe & Dohme (Australia) Pty Ltd* [2010] FCA 180, hereafter referred to as *Peterson*.

³⁵ At [927], his Honour found it was not until September 2004 that the increase in risk could have been or discovered at the necessary scientific level.

³⁶ *Ibid* [926]-[927].

³⁷ *Ibid* [2010] FCA 180, [682].

³⁸ *Ibid* [2010] FCA 180, [680]-[681].

³⁹ *Ibid* [2010] FCA 180, [929].

⁴⁰ *Merck v Sharp and Dohme (Australia) Pty Ltd v Peterson* [2011] FCAFC 128, [206].

⁴¹ *Ibid* [207].

three types; and that such classification does go towards the first question posed by this paper - when does the defence apply? The discussion in section four explains the judgment and addresses this issue in more detail.

After discussing the defence, his Honour turned his mind on to how the defence should apply to the defective product, which required a discussion of how Vioxx was defective:

on one view at least by the terms of s75AC a defect is a situation rather than a particular aspect of the composition of the goods in question. And it is a situation the existence of which must be determined as a matter of judgment only after consideration of all relevant circumstances. In the present case I have effectively held that persons generally were entitled to expect [that the defendants] would have given to medical practitioners a warning which would have conveyed some idea of the signal of risk ... The state of scientific knowledge was such as would have enabled such warning to be given.⁴²

It is his Honour's reference to a *situation* defect as opposed to the *composition* of the good which suggests his Honour had correctly applied the types of defect to Vioxx, as was intended by the Attorney-General.

His Honour went on to make further observations about the interplay between the defect and defence:

[The defence] contemplates the existence of a defect capable of being discovered by reference to the current state of scientific or technical knowledge. It is not concerned with the kind of contextual circumstances referred to in [determining the existence of a defect]. My conclusion that the respondents ought to have acted consistently with the cardiovascular risk signal yielded by VIGOR is in the nature of a judgment as to how persons generally were entitled to expect that MSDA would act. By all means it informed my determination that there was a defect, but the content of persons' expectations did not constitute the defect itself. The defect was something inherent in Vioxx as a matter of composition. I consider that the intent of s75AK(1)(c) is that if that defect could not be discovered according to the state of scientific or technical knowledge, the defence should be available, notwithstanding that enough was suspected about the product to activate an implied obligation to give warnings of the kind mentioned in s75AC(2)(d). I propose to uphold MSDA's defence under s75AK(1).⁴³

His Honour recognised that Vioxx was defective in *two* respects: instructional (situation) and design (composition). In that case, why did the defence apply? This issue will be discussed in section four.

E Reflections, so far

It appears that the two key questions in relation to this defence Australian courts are struggling with, or may face in future cases are: to what extent does the court take into account considerations which may modify or mitigate what was otherwise meant to be a strict liability regime upon manufacturers? And does it apply to all three types of defects? So far, Australian courts have avoided any

⁴² *Peterson v Merck Sharpe & Dohme (Australia) Pty Ltd* [2010] FCA 180, [928].

⁴³ *Ibid* [929].

detailed jurisprudential analysis in relation to this defence. However, this avoidance is concerning, for a number of reasons. Firstly, these cases, but for insufficient judicial treatment of the defence, had the opportunity to become seminal cases on this area of law in Australia. Instead, the courts applied this defence on a very ad hoc, case by case basis. Future cases as well as lower courts therefore have little guidance and will be forced to continue this approach. For a law that carries huge significance for both consumer groups and the business sector, this is both undesirable and unreliable.

Secondly, as was recognised by Kiefel J in *Carey-Hazell*,⁴⁴ the defence acts as a limit upon the strict liability nature of the provisions to the point that they detract significantly from the definition of strict liability. Having such a significant impact upon compensatory provisions justifies a closer look at how the defence *should* operate. In this regard, Lindgren J's question about whether and to what extent reasonability and practicality should act to modify the duties is a very valid question, as this paper has already identified.

In light of minimal assistance from precedent and academic literature, and also given the defence was derived directly from the Directive, it is necessary to visit the case law from other jurisdictions which have also domestically implemented the Directive.

IV SECTION TWO: WHAT DO OTHER COUNTRIES SAY?

This section seeks to contextualise the Australian operation of the law within the wider legal landscape by comparing the Australian approach to cases from overseas jurisdictions. It will commence with a fundamental case from the European Court of Justice, and then delve into five further cases from other jurisdictions which have also considered this defence. Again, the main questions are when and how the defence has been applied.

A *The elements of the defence: Europe*

One concerning observation about the two Australian cases is their failure to refer to European jurisprudence generally, and specifically the failure to take note of a crucial Opinion adopted⁴⁵ by the European Court of Justice contained in *European Commission v United Kingdom*⁴⁶ (the Opinion). The issue was whether the UK's difference in the defence's wording (as discussed above) meant they had failed to properly implement the Directive. In finding that despite the differences, the UK had properly implemented the Directive, *European Commission v United Kingdom* also provided significant guidance as to the elements and scope of the defence.

The Opinion summarises the essentials of this defence down to three elements: what was the most advanced state or level of knowledge; how accessible the

⁴⁴ [2004] FCA 853 [182].

⁴⁵ The Advocate-General's opinions are not binding and it is at the discretion of the judges to decide whether they should be followed. Even if they are not followed they 'may still be invoked as persuasive authority' in future cases - Josephine Steiner, Lorna Woods and Christian Twigg-Flesner *EU Law 9th Edition* 2006, 36.

⁴⁶ [1997] 3 CMLR 923.

knowledge was to the manufacturer; and whether knowledge in that particular state enabled discovery of the defect.

Firstly, in regards to the concept of scientific knowledge and epistemology, “scientific and technical knowledge” was not concerned with the practices or standards applicable in a particular industrial sector.⁴⁷ Likewise, the practicability or cost of eliminating the defect from the product was irrelevant⁴⁸ as it was known that the manufacturer had failed to keep up to date with developments in knowledge.⁴⁹ Knowledge and the manufacturer’s actions were “assessed using the yardstick of the knowledge of an expert in the sector.”⁵⁰

As for the state of knowledge, it was recognised that scientific knowledge and discoveries were uncertain matters, subject to criticism and doubt amongst the scientific community. Science is always in a state of development, so that what was once an accepted view may later become rejected and vice versa.⁵¹ Facing this, the Opinion determined the state of knowledge for the purposes of this defence would be the “**most advanced level of research** which has been carried out at a given time.”⁵² In the case of pharmaceuticals (and products generally), it would be at the time of supply onto the market.

The next element was accessibility. The defence, the Opinion held, would only operate in cases where the risks are, ‘by their nature, unquantifiable.’⁵³ The manufacturer would not escape liability where a risk was foreseeable, even if it was a minority or an isolated finding⁵⁴ as that one finding meant that the risk was no longer unforeseeable or undiscoverable. However, it was acknowledged that being able to access that finding was also vital.⁵⁵ In this regard, accessibility was affected by a number of factors, including place of origin, language of the findings, and the geographical circulation of those findings.⁵⁶ The example in the Opinion compared a study published in the United States, in an international English language journal as opposed to similar findings by an academic in Manchuria, published in a local Chinese-language journal which is not available outside of China.⁵⁷ Despite the finding of a risk having been made (and thus is reasonably foreseeable), inaccessibility of the publication would allow the defence to be effective.

The case did not provide much discussion on the element of discoverability. Rather, this element was interpreted in the context of the UK Act. The Opinion noted that the UK would interpret this element objectively, and thus by virtue of that test, the producer had to prove ‘that it was *impossible*, in the light of the most

⁴⁷ Ibid, 933.

⁴⁸ Ibid.

⁴⁹ Ibid.

⁵⁰ Ibid.

⁵¹ Ibid.

⁵² Ibid.

⁵³ [1997] 3 CMLR 923.

⁵⁴ Ibid, 934.

⁵⁵ Ibid.

⁵⁶ Ibid.

⁵⁷ Ibid.

advanced scientific and technical knowledge objectively and reasonably obtainable and available, to consider that the product was defective.’⁵⁸

B The cases from overseas

Research indicates only five discernible cases internationally that have applied this defence: three from the UK and one each from Germany and Japan. It is noted that these five cases (apart from the German case) take a hardline, pro-consumer approach in their strict interpretation of the defence and in this regard can be distinguished from their Australian counterparts.

*1. If the risk is known or discoverable: A v National Blood Authority*⁵⁹

Despite being the second UK case in line to discuss this defence, Burton J noted it was the first which would delve into detail how the defence should operate.⁶⁰ Indeed, *A v National Blood Authority*⁶¹ has been the only case to date which has analysed how the defence operates from the European jurisprudential perspective, acting as the domestic equivalent of *European Commission v United Kingdom*.⁶²

In this case, the claimants had been infected with Hepatitis C through blood transfusions where the blood or blood products were from infected donors. The risk of such infection was known but impossible to avoid either because the virus had not been discovered or because a reliable test did not exist. The claims were brought under the UK CPA, where the defendants raised article 7(e) containing the defence.

All parties agreed, and Burton J accepted, that the Directive was to be interpreted purposively.⁶³ Because of the community origins of the Directive, Burton J was mindful of the following interpretative points:

- It is proper to look at the preparatory works to determine the purpose, but with caution;
- Guidance can be obtained from the other languages in which the Directive was published in determining meaning and construction, and to promote harmony among the diverse jurisdictions within the community.⁶⁴

Burton J agreed with the claimant’s submission on the purpose: that the Directive’s primary purpose was consumer protection. Specifically, his Honour noted, its purpose is to ‘prevent injury and facilitate compensation for injury.’⁶⁵ The interpretation of the defence, as a release from such responsibility was to be

⁵⁸ Ibid, 935, emphasis added.

⁵⁹ [2001] 3 All ER 289.

⁶⁰ Ibid, [17].

⁶¹ [2001] 3 All ER 289.

⁶² *European Commission v United Kingdom* [1997] 3 CMLR 923.

⁶³ [2001] 3 All ER 289, [15].

⁶⁴ Ibid.

⁶⁵ Ibid.

interpreted narrowly and restrictively, to ensure maximum compliance with this purpose, as indicated by *European Commission v United Kingdom*.⁶⁶

As part of this narrow approach therefore, avoidability (or unavailability) of the risk of infection was not a relevant consideration in deciding whether to apply the defence. Rather, his Honour took the very narrow view that knowledge of the risk (which did exist in this case) was sufficient to exclude the defence:

If there is a known risk – the existence of the defect is known or should have been known ... then the producer continues to produce and supply at his own risk. It would ... be inconsistent with the purpose of the Directive if a producer, in the case of a known risk continued to supply products because and despite the fact that, he is unable to identify in which of his products that defect will occur, or recur, or more relevantly in a case where the producer was obliged to supply without accepting the responsibility for any injuries resulting by insurance or otherwise ... Once the existence of the defect is known then there is then the risk of that defect materialising in any particular product.⁶⁷

As a result, some products might qualify, but only once, for once the defence is triggered, it means that the defect was once not known, but later discovered (usually by the time the lawsuit commences) and thus future attempts to trigger the defence would not be successful.⁶⁸ The defence is meant to protect the producer in respect of the unknown. A risk which is known but unavoidable would not qualify.⁶⁹

This was Burton J's primary finding. However, his Honour also considered the alternative argument from the defendant: that due to the unavailability of a specific test and the inadequacy of surrogate tests, the defendants did not have the opportunity to discover the defect and thus, scientific knowledge did not enable, or could not be accessed to assist with discovery.⁷⁰ Enable, Burton J noted, was treated in other languages as the equivalent of "to permit."⁷¹ In this case, surrogate testing would have permitted discovery of the infection in the blood, or at the very least a provisional discovery of the defect, or may have enabled subsequent discovery of the virus if the blood was re-examined or re-tested later.⁷² As for accessibility, his Honour noted that at the relevant date, both surrogate testing and appropriate screening procedures were available and thus, the knowledge was accessible.⁷³ It was irrelevant that time was required to implement the necessary precautions into the domestic system, taking into account such practical considerations would conflict with the strict and stringent approach of *European Commission v United Kingdom*.⁷⁴

⁶⁶ [1997] 3 CMLR 923 [51], [64], [75].

⁶⁷ [2001] 3 All ER 289 [74].

⁶⁸ Ibid [77].

⁶⁹ Ibid [76], [78]. They may however, not be regarded as 'defects' to begin with if they are known and socially acceptable and thus reasonably within consumer expectations.

⁷⁰ Ibid [183].

⁷¹ Ibid.

⁷² Ibid.

⁷³ Ibid [184].

⁷⁴ Ibid.

The final and vital question was the concept of discoverability. On this element, his Honour's question was whether the defendants could prove, on the balance of probabilities that surrogate testing would not have led to the discovery of infection in the donated blood.⁷⁵ As the evidence demonstrated that on the balance of probabilities, surrogate testing and/or routine screening would have discovered the infection and thus, the alternative case also failed.⁷⁶

2. *Knowledge is sufficient: Richardson v LRC Products Ltd*⁷⁷

In this case, the claimant sought damages under the UK Act from a condom manufacturer, for an unwanted pregnancy arising out of a broken condom. The claim was ultimately unsuccessful, but Kennedy J made comments in obiter that if the claim was successful, the defence would not have been available to the defendant. The defence was only available where the defect was of a nature that scientific or technical knowledge was ignorant of it.⁷⁸ It would not protect a defendant where a defect was known, but there was merely 'no test which is apt to reveal its existence in every case.'⁷⁹ This case preceded *A v National Blood Authority*⁸⁰, but had Kennedy J's comments been ratio decidendi, they would have been affirmed by Burton J.

3. *Some simple tests were sufficient: Abouzaid v Mothercare*⁸¹

In this case, the risk of injury to the eye from a recoiling elastic buckle was held to be outside the realm of scientific and technical knowledge. This defence contemplated 'scientific and technical advances which throw additional light ... on the propensities of materials and allow defects to be discovered.'⁸² On the other hand, this risk was one which was easily discovered had the manufacturers conducted simple tests, which they had not undertaken.⁸³ The defence therefore provided no assistance and was not considered relevant as there was no advance in the scientific or technical realm.

4. *"The one that got away": German Bottle Case*⁸⁴

In this case, the question turned on whether the defence applied to an exploding glass bottle which 'unavoidably got away despite the exercise of all appropriate precautions' in quality control⁸⁵. The cause of the explosion was a hairline crack, which the court defined as a manufacturing defect. On the basis of this, and despite expert opinion that there was an "irreducible residual risk", the defence did not apply:

⁷⁵ Ibid [186].

⁷⁶ Ibid [187].

⁷⁷ *Richardson v LRC Products Ltd* (2001) 59 BMLR 185.

⁷⁸ Ibid 193.

⁷⁹ Ibid.

⁸⁰ [2001] 3 All ER 289.

⁸¹ *Iman Abouzaid v Mothercare (UK) Ltd* [2000] EWCA Civ 348 (21 December 2000).

⁸² Ibid [29] (Pill LJ).

⁸³ Ibid [46] (Chadwick LJ).

⁸⁴ Translated version of the judgment located by P Schlechtriem, B Markesinis and S Lorenz, *Decisions of the Federal Court of Justice* (9 May 1995) Comparative Law Society <<http://www.iuscomp.org/gla/judgments/tgcm/z950509.htm>>.

⁸⁵ Ibid.

Manufacturing defects which ‘get away’ do not, simply because they cannot be avoided by any proper precautions, constitute defects unascertainable in the current state of scientific or technical knowledge. ... The purpose of this rule is merely to exclude liability for what are termed development risks; the term only covers cases where at the time a product was put into circulation none of the means offered by the current state of science and technology rendered it possible to detect its dangerous quality. The strict liability of the producer is to be limited by what is objectively possible in the light of knowledge of risks available at the time the product is put into circulation. The only dangers to be treated as development risks are dangers inherent in the design and construction of the product, which in the current state of technology could not be avoided, not those that were inevitable at the stage of production ... Liability is to be excluded only if the potential danger of the product was unrecognisable by reason of the fact that at the time of circulation it was not yet possible to recognise it. It is no longer a defence that the defective product ‘got away’.⁸⁶

Unavoidability or inevitability per se therefore was not enough. Rather, it had to be a result of science or technology not being at the stage that the risk or defect could be discovered. Manufacturing risks, while inevitable, were discoverable; design defects on the other hand were more likely to be inevitable due to undiscoverability.

5 “*The defendant should have made the connections*”: *Snapper Fish Case*⁸⁷

In a 2002 Japanese case from the Tokyo District Court, patrons contracted food poisoning after having eaten snapper sashimi. In determining whether the defence should apply, and unlike the UK cases, the Court did consider external factors: in this case, acknowledging that ‘industrial capacity could be undermined if manufacturers scaled back research and development because they could not foresee harms arising from defects and scope of liability.’⁸⁸ Yet, despite acknowledging the negative impact strict liability could have on industry, innovation and economy, the Court decided to prioritise compensation for injured parties over all else.

To reduce uncertainty, the Court defined knowledge as “all knowledge” available to deciding whether a product was defective, ‘building on the results of all disciplines related to science and technology objectively existing in society as a whole; and that the applicable standard was the world’s highest standard obtainable when the product was delivered.’⁸⁹ The Court noted the defendant had read relevant literature about infected snapper, and more importantly, the literature had pointed out there were reports of infected fish in the defendant’s prefecture. The risk of infected snapper was therefore foreseeable as the defendant could have made the necessary connections. The defence was not available.

⁸⁶ Ibid.

⁸⁷ I owe my understanding of this case to a summary provided by Dr Luke Nottage, *Japan – PL Law Case Notes, PL Law Case No 29 Snapper Fish Case 1033 Hanji 54* (undated) University of Sydney
http://sydney.edu.au/law/anjel/documents/2010/BIICL_Japan_PL_Law_Case.pdf.

⁸⁸ Ibid.

⁸⁹ Ibid.

V SECTION THREE: THE ACADEMIC LITERATURE

This section considers academic commentary⁹⁰ from leading authors on the two approaches of this defence. Generally, they all agree that the essence of the defence can be summarised by the three elements as stated in *European Commission v United Kingdom*. That is where the similarities end and the literature on how the defence should be interpreted diverge into the strict approach and the reasonable approach. This part of the paper will review the literature and use it to put the case law into some perspective.

A The concept of “knowledge”

The Opinion defined ‘knowledge’ to have two characteristics: that it was objective so that knowledge, business considerations or specifications peculiar to the industry was irrelevant; and that the yardstick would be the ‘most advanced level of research’ available at the time.⁹¹

Just how realistic are these two requirements in the scientific realm? Even the Opinion recognised that scientific knowledge faces uncertainty, doubt and conflicting theories. However one perceives knowledge, certain inherent difficulties about scientific and technical knowledge remain the same.

The first is the difference of opinion or interpretation over the same set of facts. As Teff notes, in lawsuits, a major obstacle in evidence is that scientific or medical researchers may legitimately hold conflicting views: ‘there will often be a great area between speculation, hypothesis or information on the one hand and hard knowledge on the other.’⁹² A second is that knowledge, especially in the case of new products will require time to emerge, ‘the reality is both scientific and technical knowledge are dynamic.’⁹³ The price of scientific progress is uncertainty.⁹⁴ Specifically in the case of new pharmaceutical drugs:

the law... recognises the importance attached to innovation. In determining the level of acceptable risk for new drugs, allowance will be made for the fact that they need to be potent to be useful and that there are practical limits on discovering risks at the stage of pre-market testing on relatively small populations in animals studies and clinical trials.⁹⁵

⁹⁰ Christopher Hodges, ‘Development Risks: Unanswered Questions’ (1998) 61 *Modern Law Review* 560; Christopher Hodges, *Unknown Risks and the Community Interest: the Development Risks Defence in the Product Liability Directive* (December 1996) McKenna and Co, <<http://legacy.library.ucsf.edu/tid/hlz23a99/pdf;jsessionid=D520F7CDABEC19973F42EC5753FF5023.tobacco03>>; Charles Pugh, Marcus Pilgerstorfer, ‘The Development Risk Defence – Knowledge, Discoverability and Creative Leaps’ (2004) *Journal of Personal Injury Law* 258; Mark Mildred and Geraint Howells, ‘Comment on Development Risks: Unanswered Questions’ (1998) 61 *Modern Law Review* 570.

⁹¹ [1997] 3 CMLR 923, 933.

⁹² Harvey Teff, “Products Liability” in Ian Kennedy, Andrew Grubb, Judith Laing and Jean McHale (ed) *Principles of Medical Law* (Oxford University Press, 3rd ed, 2010) 967, 980.

⁹³ Hodges (1998) above n 90, 566.

⁹⁴ Newdick (1991), above n 3, 312

⁹⁵ Teff above n 92, 980.

Secondly, there may very likely be disagreement over what even is the 'most advanced' level of knowledge at a given time.⁹⁶ In reality, manufacturers usually have 'no option but to accept the prevailing state of knowledge, which in some circumstances may mean the majority view.'⁹⁷ Certainly, the Opinion's interpretation of the knowledge as discussed above, while not impossible to apply, does raise more complex questions than it answers.

A third problem associated with the strict approach as advocated by the Opinion in regards to knowledge is the burden on the manufacturer to take into account a minority view about whether a risk exists. In the case of pharmaceuticals and warning defects, Hodges notes that the manufacturer may be 'faced with enormous cost in warning against a plethora of hypothetical defects, which would undermine the impact of genuine defects.'⁹⁸ There is also the interference by third party regulatory bodies over the permitted wording of warnings and labels:

The minority view (that the pharmaceutical product is defective) might be disproved by further research. [The manufacturer's] ability to make any amendment is in fact limited since the wording of summaries of product characteristics is subject to approval by a competent authority and cannot be changed without the authority's consent. The experience is that the authorities are unlikely to permit wording based on minority but unaccepted theories.⁹⁹

Theoretically, it is not impossible to comply with the strict interpretation. In developing a pharmaceutical and determining instructional wording, a company could take into account all scientific views about the risks of a particular design, all levels of knowledge and all existing scientific theories. The practical effect of this however is that a new drug may never be developed, or never be released into the market. At what point does the knowledge stop? Related to this issue of the theoretically possible infinite research and development process is the element of discoverability.

In the pharmaceutical context, Stapleton offers an alternative view, rather than attempting a definition of what is knowledge, she isolates the type of knowledge and analysis which would be most relevant to pharmaceutical drugs:

the state of epidemiological data set relating to corrections between use and adverse experience. It is this data set and this alone which, with appropriate mathematical analysis, enables the deleterious effects of the drug's chemical design to be firmly established without scientific confidence, that is 'discovered'.¹⁰⁰

B Accessibility: from books to biology

*EC Commission v United Kingdom*¹⁰¹ was decided in 1997. Given the "state of knowledge" about networks and online resources back then, it is understandable why the Opinion thought that expecting a US manufacturer to be able to access and understand a Manchurian article published in a Chinese journal was

⁹⁶ Hodges (1998) above n 90, 568.

⁹⁷ Ibid 568.

⁹⁸ Ibid.

⁹⁹ Ibid.

¹⁰⁰ Stapleton (2007) above n 3, 1021.

¹⁰¹ [1997] 3 CMLR 923.

unreasonable.¹⁰² It is questionable whether the same can be said today. With the existence of online databases, research repositories and a general emphasis on knowledge dissemination, geographical boundaries no longer pose the same difficulties that they may have in 1997. Indeed, technological advances have allowed today's businesses to access a much larger pool of information, mostly online. As Mildred and Howells point out, with online access now available regardless of industry, 'there is no need to confine discoverability by accessibility to a particular sector.'¹⁰³ As for language, professional interpreters would assist, although it is acknowledged they may struggle with some technical language.

From this one concession, could it be argued then that the ECJ is not as strict as first appears? If impossibility is the standard manufacturers must aspire to in order to satisfy this defence, and practicality and monetary costs are to be ignored, then the 1997 Manchurian example has little effect. It is reasonable to assume, a US company would have industry links to China and could potentially become aware of this new discovery. Viewed from this position, the hypothetical suggested in the ECJ fails its own standard of impossibility. It could be inferred that the Opinion is in fact acknowledging (albeit unwillingly) that external considerations must be taken into account in determining accessibility.

There is one practical aspect of the industry that could render accessibility impossible. In an industry as competitive as science and technology, and especially pharmaceuticals, implications of intellectual property laws, protecting trade secrets and confidential research and development will pose significant barriers to accessing the most advanced level of knowledge. Will the courts be willing to take this into account? Currently, there appears to be some small but definitive moves in the American pharmaceutical and life sciences sector to collaborate by pooling knowledge about drug development into a "globally accessible private cloud" and sharing clinical trial data.¹⁰⁴ Unfortunately, the same cannot be said about the European pharmaceutical industry. Based on recent reports, it appears to oppose attempts at transparency by the European Medicines Agency (EMA) (via disclosure of clinical trial data) for fear that transparency would affect competition.¹⁰⁵ Two companies have already commenced action against the EMA in an attempt to block disclosure.¹⁰⁶

While the European affairs are unfortunate, if the EMA does succeed with this move, and such collaborative research efforts continue, intellectual property and trade secret considerations will no longer pose the same difficulties to accessibility as they currently do. Overall, it is submitted that physical

¹⁰² Ibid 934.

¹⁰³ Mildred and Howells above n 90, 572.

¹⁰⁴ Dan Munro 'SAS and GSK Pull Big Pharma into Big Data Collaboration' *Forbes* <<http://www.forbes.com/sites/danmunro/2013/06/27/sas-and-gsk-pull-big-pharma-into-big-data-collaboration/>>; Jeanne Whalen, "Roche, Astra to Share Drug Research Data" *Wall Street Journal* <<http://online.wsj.com/article/SB10001424127887323998604578567682985587790.html>>.

¹⁰⁵ Makiko Kitamura, "Sanofi Chief Says EU Clinical 'Data Dump' to Hurt Drugmakers" *Bloomberg* (Online) 24 June 2013 <<http://www.bloomberg.com/news/2013-06-24/sanofi-chief-says-eu-clinical-data-dump-would-hurt-drugmakers.html>>.

¹⁰⁶ Ibid.

accessibility is no longer the real question and eventually, the nature of accessibility will become a moot point.

C Enabled discovery

As noted previously, the Opinion discussed the element of discovery in the context of the UK CPA, again imposing the standard of impossibility. Yet, as Mildred and Howells note, what is undiscoverable?¹⁰⁷ It is on this issue that there is the clearest divide between the academics who have written on this area. Advocating for the strict, textual interpretation are Pugh and Pilgerstorfer,¹⁰⁸ approaching the defence from a European, civil law system background, arguing for an operation where the manufacturer may only be excused for unquantifiable risks, and reasonableness of the manufacturer's actions being irrelevant. They firstly cite the Opinion to support their stance. Secondly, they note that the Opinion makes no mention of whether risks were "reasonably" quantifiable or unquantifiable; rather, merely whether it was "impossible" for the defect to be discovered. Next, they contrast the civil law system to the common law system, highlighting that the Opinion was written in the environment of the former, which does not recognise concepts such as 'negligence, duties of reasonable care and foreseeable risks.'¹⁰⁹ The standard of "reasonableness" therefore challenges European legal jurisprudence, which forms the foundation of their argument that the strict approach is the preferred approach.

Pugh and Pilgerstorfer¹¹⁰ apply their strict approach to pharmaceutical drugs, and conclude a narrow interpretation is not unfair to manufacturers any more than the circumstances already require. They note that drug developers are required to conduct the relevant tests or trials to determine the side effects, no matter how rare or unexpected they may be. Therefore, 'provided the science/technology is in place to make it possible to either test for the [side effect] in a particular product or to know about its presence, the defence would be lost.'¹¹¹

On the other hand, there are authors who note that the practical realities of business and industry (especially that of pharmaceuticals) necessitates leniency in the form of reasonableness. When one takes into account three major external limitations to the defect discovery process, it can be seen that this is the preferable interpretation of this element. These are commercial practicalities and government response and regulation; ethical constraints on the drug development process, and delays in the timely access of medicines by patients.

In regards to the first, both Hodges and Newdick point out that in quality control situations, commercial considerations are compulsory.¹¹² As for pharmaceuticals, Hodges writes:

If testing were required to continue until all possible risks which might occur with use of a product had been identified, few producers could afford to innovate and

¹⁰⁷ Mildred and Howells above n 90, 571.

¹⁰⁸ Pugh and Pilgerstorfer above n 90, 263-265.

¹⁰⁹ Ibid.

¹¹⁰ Pugh and Pilgerstorfer above n 90, 267 – 268.

¹¹¹ Ibid 267.

¹¹² Newdick above n 3, 469.

consumers would not benefit from advances in science and technology. Research would stagnate if denied practical application and commercial advantage.¹¹³

Hodges also alludes to the unfairness of imposing such stringent requirements on the industry. Facts and data, he writes, may be known, but the industry may not have sufficient time then to understand the significance of that data or a link to the existence of a defect.¹¹⁴ As ‘the benefit of hindsight cannot be overlooked,’¹¹⁵ this supports a reasonableness approach to this element. To impose too strict an approach may turn this issue into what Newdick refers to as a “criterion of luck”, in which case defence is successful only if the defendant is lucky enough to come across the relevant discovery.¹¹⁶ Or in the case of the American company having links to the industry in China, they may not be lucky enough to have sufficient links to come across the knowledge. For the success of a legal defence to turn on how much luck a company has would be absurd and uncertain. Rather, the question to ask should be ‘how much testing it is *reasonable* to expect’ of the manufacturer.¹¹⁷

Another restraint which acts as a qualification to the theoretical possibility of unconditional, unqualified discoverability of a defect or a risk is ethical limitations. As Stapleton¹¹⁸ points out, ethical means of discovery should act as a reasonable restraint on this issue and the otherwise limitless (and sometimes immoral) possibilities. If the strict interpretation and the impossibility of the discovery were adopted, does this mean that manufacturers must engage in all the possibilities of discovery, both ethical and unethical, as part of establishing this defence? Public policy, as well as common sense dictates that it not be so, and even if such means was required by the defence, it would be foreseeable that research ethics committee panels would not allow unethical practices to be undertaken.

Finally, there is also the reality of limited time. In theory, discoverability of a defect is not impossible, given enough time, ‘any defect can be discovered prior to marketing given sufficient testing.’¹¹⁹ Since absolute impossibility of discoverability is in itself absolutely impossible, the defence would be rendered nugatory.¹²⁰ In addition, unlimited time is not a reasonable allowance in research, especially when balanced against the need to ensure timely access of pharmaceuticals by patients. In the US, the Food and Drug Administration’s drug approval process is commonly criticised for impairing the timely release of vital and life-saving pharmaceutical drugs, and have in recent years introduced accelerated approval procedures in response to such concerns by focusing more on how much promise the drug shows during the clinical trial process.¹²¹

¹¹³ Hodges (1998) above n 90, 561 – 562.

¹¹⁴ Ibid 567.

¹¹⁵ Ibid 567.

¹¹⁶ Newdick above n 3, 311.

¹¹⁷ Hodges (1998) above n 90, 568, emphasis added.

¹¹⁸ Stapleton (2007) above n 3, 1024.

¹¹⁹ Hodges (1998), above n 90, 568.

¹²⁰ Stapleton (2007) above n 3, 1025.

¹²¹ Gardiner Harris, “FDA Officials, Hoping to Stave Off Critics, Point to Increased Drug Approvals” *New York Times* (

VI SECTION FOUR: THE DEFENCE AND PHARMACEUTICALS IN AUSTRALIA

This section provides some explanation for the divergence observed in the case law, as well as incorporates discussion from the academic literature, supporting the following two claims: that the defence should only apply in cases of design and (in some cases) instructional defects; and that when the defence does apply, a reasonable interpretation should be preferred over strict.

A *Explaining the divergence*

Currently, the case law environment can be summarised thus. In Australia, the opportunity to consider the scope and extent of the defence has never truly arisen. In *Graham Barclay*¹²² it was not necessary. In *Peterson*¹²³, the defence was assumed to operate from a reasonableness standard, and also, notably, the type of defect (design) observed in the medication was also relevant to finding the defence applicable.

From the overseas perspective, the *German Bottle Case*¹²⁴, while the Court did not make it explicit, their reasoning appears to be similar to that of *Peterson*. Unavoidability of the defect did appear to be a factor towards determining whether the defence applied, as well as the type of defect. In this case, as it was one related to the stage of production of the bottle, it was a manufacturing defect, and thus, the defence was automatically excluded. The remaining four overseas cases expressly stated the defence was to be interpreted to the narrowest extent possible.

*EC Commission v United Kingdom*¹²⁵ however, is somewhat ambivalent. On the one hand, it expressly rules out practicability in considering the content of knowledge. It then acknowledges that viability of accessing the relevant information is indeed relevant, thus effectively reintroducing the question of practicability and, to some extent, reasonableness into the formula. However, it finishes by applying to the issue of discoverability, the standard of impossibility, which is in itself impossible, since given time, anything can be discoverable.

What might explain this seemingly arbitrary divergence between the cases, which all considered the same law? Determining the reason for the differences is made more difficult by the fact that only *A v National Blood Authority*¹²⁶ provides detailed jurisprudential analysis. Three reasons are put forward. The first is a broader problem observed in the regime generally and that is the failure by lawmakers to prioritise their policy objectives, contributing to judicial confusion over how to reconcile conflicting objectives. The second is a more specific

< <http://www.nytimes.com/2011/11/04/health/policy/drug-approvals-rise-for-fda.html>>; Avik Roy, "Should the FDA Approve More Drugs After Phase II? A Response to Matthew Herper" *Forbes*

< <http://www.forbes.com/sites/aroy/2012/05/04/should-the-fda-approve-more-drugs-after-phase-ii-a-response-to-matthew-herper/>>.

¹²² [2000] FCA 1099.

¹²³ [2010] FCA 180.

¹²⁴ Schlechtriem, Markesinis and Lorenz, above n 84.

¹²⁵ [1997] 3 CMLR 923.

¹²⁶ [2001] All ER 289.

problem, the court's failure to recognise the importance of distinguishing the types of defects. The third is pharmaceutical specific, and that is that overseas courts which have applied the defence simply have not had the opportunity to apply it to pharmaceuticals.

1 Failure to lay out priorities

Among other policies, the Directive was formed, and domestic implementations allowed on the back of what could be seen as two competing policy objectives, consumer protection versus business efficacy. The introduction to the Directive setting out its desired policies includes the following statements:¹²⁷

Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;

Whereas protection of the consumer requires that all producers involved in the production process should be made liable, in so far as their finished product, component part or any raw material supplied by them was defective ...;

Whereas, to protect the physical wellbeing and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect...;

Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances.

However, the Directive did go on to acknowledge that the state of the art defence may act to 'restrict unduly the protection of the consumer' and thus offered member states the discretion to include the defence. Therefore, although the Directive did not explicitly state the order of priorities, the reference to the consumer expectations test and recognition that member states may be reluctant to impose a restriction on consumer rights implies that the latter was certainly prioritised over fair apportionment of risk and fairness to the business industry. There is also, as Pugh and Pilgerstorfer highlighted, the differences between the common and civil legal systems, and the latter does not recognise concepts of negligence and reasonableness.

Can Australian courts justify a departure from this approach? I would say yes. I would also additionally submit that the UK could likewise make a similar departure. Although the Directive is European in origin, upon domestic implementation, it is only appropriate that domestic legislation be interpreted and applied according to the legal tradition of that jurisdiction. Stapleton provides a political reason as to why an objective reasonableness test should be adopted. One of the policy objectives which supported inclusion of the defence in the statutory regime was the protection of innovation. This was the case in both Australia and the UK. Indeed, for the UK, it was one of the key "sweeteners" to

¹²⁷ Council Directive 85/374/EEC [1985] OJ L 210/29.

sign up to the Directive.¹²⁸ Noting this, Stapleton writes that this political context supports the view that the defence will protect the manufacturer where they:

did all that the public interest could reasonably require, where reasonableness ... is a normative question for the court. ... The aim was that accidents which were either unforeseeable or given a practice rightly adopted by a manufacturer, considered to be unavoidable would not be the subject of liability.¹²⁹

Yet, as can be seen in the UK cases, courts have gone the other way in ensuring that businesses, while not left unprotected, have a much more difficult standard to satisfy to gain this protection. It appears that the UK courts have been much more pro-active in self-directing their own set of priorities, so that consumer protection is placed above business protection. The same could be said of Germany and Japan.

In Australia, lawmakers also wanted to ensure business efficacy and technological innovation would not be affected by a consumer protection regime, but as was observed in section one, parliament never addressed the question of which would override the other in case of conflict. As a result, without a clear set of priorities, it appears that Australian courts have tried to accommodate as many of the objectives as possible, thus the divergence with their European counterparts.

It is beyond the scope of this article for a detailed discussion of this issue, and is raised for future consideration. In considering the concept of 'consumer protection', to focus on compensation, product quality and easing the burdens of litigation is simplifying the matter. In the context of pharmaceuticals, consideration must also be given to issues such as medical innovation, health and timely access to medications, which go towards patient well-being. As discussed above, a strict interpretation of the defence would have a negative impact on scientific innovation and the timely release of new and experimental medications.

2 *Failure to distinguish defects*

At the beginning of this article, it was noted the Attorney-General's express intention that the definition of "defect" would operate on the understanding that there were three types of defects. Australian lawmaker's emphasis that businesses would be held financially and legally responsible for their products on the basis of control was also discussed. Finally, emphasis was placed on Jessup J's recognition that Vioxx suffered both a design and an instructional defect.¹³⁰

Out of the three types of recognised defects, in the pharmaceutical context, manufacturing defects would be that which could be regarded as most controllable and avoidable. Whether it is the combination of two chemicals leading to a toxic mix (construction) or contamination during the production and assembly process, these are external circumstances manufacturers are able to control to a large extent. On the other hand, the design of a drug and its interaction with individual physiology and other medications is an issue manufacturers' cannot fully eliminate and thus, their control is severely diminished. The defence was brought

¹²⁸ Teff above n 92, 999.

¹²⁹ Stapleton (2007) above n 3, 1025.

¹³⁰ *Peterson v Merck Sharpe & Dohme (Australia) Pty Ltd* [2010] FCA 180, [928].

in to reflect this fact, and to mitigate against too strict a regime for faults that businesses should not be strictly liable for.

Viewed in this way, it is submitted this is why the fact that the defect was associated with production was vital to the German Federal Court's application, and the Court's reasoning is more consistent with Australian lawmaker's intentions. The remaining four overseas cases failed to distinguish between the different types of defects, or dealt with it in an unsatisfactory manner, from an Australian point of view. In *A v National Blood Authority*¹³¹, the closest Burton J came to such an exercise was to dismiss any such differentiation, writing that the only relevant consideration was whether it was known or unknowable. In the remaining two UK cases and the Japanese case, there was no discussion about such differentiation. While one may argue to each country's court his Honour's own, it is important to consider the precedent value of these cases to determine whether and to what extent they should be followed. When contextualised against the legislative history, it can be seen that for Australian courts, the differentiation is far from irrelevant.

If the above reasoning is correct, Jessup J's decision to allow the defence in the face of a design defect is justified. On the other hand, his Honour also noted that Vioxx suffered an instructional defect, but it appears the design defect was the deciding factor.¹³² Should the defence have been extended to cover the instructional defect in this case? I am reluctant to offer a definite answer, and will make some observations relevant to this question. As Hodges alluded to above, manufacturers have to undertake a balancing exercise in determining which risks or side-effects are serious, more likely to occur and thus do warrant a warning. In addition, warning labels are subject to third party drug regulatory approvals, whose opinion may differ with the manufacturer as to the content of the warnings. Finally, there is also a risk/benefit analysis, to warn of every potential side effect associated with the drug may cause unnecessary and exaggerated fears in patients, who may overlook the therapeutic benefits offered. These are considerations which should form part of the reasonableness interpretation of the defence when future courts are faced with a pharmaceutical which is defective instructionally.

3 *Blood, buckles, and bottles are not drugs.*

Outside the US, Australia is the first country to have considered a pharmaceutical product liability case to this extent and applied the defence to such a product. Another reason for the divergence observed may simply be that because other courts have not considered pharmaceutical drugs, an opportunity not having yet arisen for them to apply a complex law to a unique and unpredictable product. One way to illustrate the significance of this is with reference to the most controversial element of the defence: discoverability.

To determine discoverability of a defect may be a misleading task. As Pugh and Pilgerstorfer highlight, this element is only concerned about the ability to discover the defect 'as opposed to solving, rectifying or avoiding its occurrence.'¹³³ With

¹³¹ [2001] All ER 289.

¹³² *Peterson v Merck Sharpe & Dohme (Australia) Pty Ltd* [2010] FCA 180, [929].

¹³³ Pugh and Pilgerstorfer, above n 90, 262.

pharmaceutical drugs, the last few options are not available, as side effects and adverse reactions are an inherent risk of such products. The authors cite *A v National Blood Authority*¹³⁴ and *Abouzi*¹³⁵ as examples of domestic courts endorsing the strict interpretation (both cases having been discussed above). While such reasoning is logical and applies to their respective products, it cannot be as easily applied to pharmaceutical drug: while safe, clean, uncontaminated blood is a possibility, there is no such thing as a safe drug. Buckles can be recalled and consumers can exercise a rational choice to choose one brand of baby furniture over another. Defects can be designed out of buckle structure; side effects cannot be entirely designed out of a drug. Pharmaceutical drugs are prescribed by a health practitioner, consumed by the patient under the pressure of sickness and illness, in the hope that therapeutic benefits will outweigh the risks. Patients may request that they switch to another drug to avoid one set of side-effects, and will most probably find themselves facing another set. Such was the case with Vioxx, as one of the key attractions upon its initial release onto the market was the fact that it did not cause stomach ulcers and bleeding, a problem associated with the older anti-inflammatory drugs.

B The defence reflects the scientific developments of the times

Finally, keeping in mind that prescription medication can be supplied over a long term periodically, the manufacturer has an ongoing duty to keep informed of the developments in the state of scientific or technical knowledge and incorporate these into the product, where possible. The defence is not meant to be a permanent immunity, so that even if the manufacturer were able to argue it once, if between then and the next lawsuit, a defect has been (or could reasonably be) discovered which can be eliminated by reasonable means, then it would no longer be available.

VII FINAL REFLECTIONS

As controversial a law such as this will require more debate and analysis to clarify and this paper certainly does not purport to solve all problems associated with this defence. Rather, the main premise is to argue that clarification about the operation of this defence is required in Australia, starting with the questions of when and how it should apply in the case of pharmaceutical product lawsuits, as well as offering some reflections for future discussion.

The first is questioning the necessity of the defence. Since it is only triggered where a pharmaceutical drug is found to be defective, the test for safety defect (consumer expectations) may need to be reconsidered.¹³⁶ Mildred and Howells point out that if a defect was in fact undiscoverable, a consumer would not expect discovery, and thus there would be no defect.¹³⁷ In the case of pharmaceuticals, if in theory a judge found that a reasonable consumer could not expect: firstly that a pharmaceutical to be entirely free from the possibility of adverse reactions; secondly, this particular adverse reaction could not reasonably be discovered at

¹³⁴ [2001] All ER 289.

¹³⁵ [2000] EWCA Civ 348 (21 December 2000).

¹³⁶ Mildred and Howells above n 90, 571.

¹³⁷ Ibid.

the time of supply; and finally, the adverse reaction was still reasonably undiscoverable at the time of the lawsuit; then in effect, the defence has been incorporated into the test of defect. One major problem with this reform however is that the burden of proof upon the plaintiff consumer increases significantly, possibly to the point of impossibility as consumers are unlikely to be able to access the necessary scientific or technological information necessary to make such a claim. Such an increase of the burden of proof is unacceptable.

Secondly, as the discussion in section four has hinted at, a risk/benefit analysis may be a critical issue also in determining when and how the defence should apply. It is beyond the scope of this article to explore this topic, but it is raised as a relevant consideration. Although a balancing exercise of this nature is never straightforward and will always attract controversy, it must be remembered that we are dealing with a law which is founded on the basis of scientific knowledge and development. Scientific knowledge, as scientist and Nobel Prize winner Richard Feynman stated in 1955, 'is a body of statements of varying degrees of certainty, some most unsure, some nearly sure, none absolutely certain.'¹³⁸ This statement could easily embody the philosophical basis underlying the state of the art defence, and gives an indication of the difficulty that courts will face in the future in determining the scope of this defence as best they can.

¹³⁸ Richard Feynman, *The Pleasure of Finding Things Out: the Best Short Works of Richard P Feynman* (Basic Books, 2005) 146.