IN THE COURT OF APPEAL OF NEW ZEALAND

I TE KŌTI PĪRA O AOTEAROA

CA505/2018
[2019] NZCA 660

BETWEEN	ROCHE PRODUCTS (NEW ZEALAND) LIMITED Appellant
AND	LESLIE NORMAN AUSTIN Respondent

Hearing:	19 September 2019
Court:	Kós P, Brown and Goddard JJ
Counsel:	J A MacGillivray for Appellant G J Thwaite and J Y Kim for Respondent L M Hansen for Accident Compensation Corporation
Judgment:	18 December 2019 at 3.00 pm

JUDGMENT OF THE COURT

A The appeal is allowed in part.

B The claim for compensatory damages is struck out.

C Leave is reserved for Mr Austin to file an amended pleading seeking compensatory damages in respect of self-administration of Roaccutane (prescribed for other persons) which was not prescribed for him by a registered health professional from whom he sought treatment.

D Costs lie where they fall.

REASONS OF THE COURT

(Given by Brown J)

Introduction

[1] For many years the respondent (Mr Austin) took for the treatment of acne the prescription-only drug Roaccutane, distributed in New Zealand by the appellant, Roche Products (New Zealand) Limited (Roche NZ). He claimed that such use caused a range of medical problems relating to the ossification of his spine for which he received medical treatment, including surgery, from 1993 to 2016. On 11 December 2015 the Accident Compensation Corporation (the Corporation) granted his claim for cover for diffuse idiopathic skeletal hyperostosis (DISH) of his cervical spine secondary to his use of Roaccutane. He received payment from the Corporation for 80 per cent of his lost income for two years until turning 65 on 11 January 2017.

[2] On 23 December 2016 he commenced a proceeding against Roche NZ alleging negligence in connection with the distribution of Roaccutane in New Zealand and seeking both compensatory and exemplary damages. Application was made to strike out the entire claim as being time barred and, in the alternative, the compensatory damages claim as barred by s 317 of the Accident Compensation Act 2001 (the Act). The strike out application was dismissed in a judgment of Associate Judge Christiansen who considered that the issues raised were incapable of proper consideration without full evidence being heard.[1] Roche NZ's application for review of that decision, transferred to this Court by consent,[2] is the subject of this judgment.

[3] The agreed issues for determination are:[3]

> 1 Did the Associate Judge err in refusing to strike out [Mr Austin's] claim for compensatory damages as barred under s 317 of [the Act] on the basis that [he] has cover under that Act?

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1 *Austin v Roche Products (New Zealand) Ltd* [2018] NZHC 208 at [45], [48] and [54].

2 Under s 64 of the Judicature Act 1908: *Austin v Roche Products (New Zealand) Ltd* HC Auckland CIV-2016-404-3299, 6 August 2018 (Minute of Muir J). A notice of appeal was not required: r 31(5) of the Court of Appeal (Civil) Rules 2005; and *Roche Products (New Zealand) Ltd v Austin* CA505/2018, 12 September 2018 (Minute of Clifford J).

3 In an Agreed List of Issues in accordance with r 42A of the Court of Appeal (Civil) Rules.

2 Does the case of *G D Searle & Co v Gunn*[4] apply on the facts of this case and, if so, should this Court follow that decision or should the claim be struck out as time barred under s 4 of the Limitation Act 1950?

3 Is [Mr Austin's] contention that he may be entitled to an extension of time under s 28 of the Limitation Act 1950 clearly untenable?

Because a finding in favour of Roche NZ on the second or third issues would be determinative of the entire claim, we commence with the second issue, but address its two limbs in reverse sequence.

The status of *G D Searle & Co v Gunn*

[4] Under s 4(7) of the Limitation Act 1950 (the 1950 Act) a claim in respect of bodily injury was required to be brought before the expiration of two years from the date on which the cause of action accrued.[5] The 1950 Act did not define when a cause of action accrued but the "conventional view" was that time began to run as soon as a wrongful act caused personal injury beyond what could be regarded as negligible, whether or not the damage could be discovered.[6]

[5] The conventional approach was affirmed by the Privy Council in *Invercargill City Council v Hamlin*.[7] Their Lordships explained that in the case of a latent defect in a building the element of loss or damage necessary to support a claim for economic loss in tort does not arise so long as the defect is unknown, and the market value of the building is unaffected.[8] In latent defect cases knowledge or discoverability affects when the loss occurred. These cases do not represent a departure from the orthodox focus on occurrence of loss rather than on discoverability of a loss which had already occurred.[9]

[6] However in *Searle*, which concerned a disease contracted following the insertion and removal of an intrauterine device, this Court endorsed a test of

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4 *G D Searle & Co v Gunn* [1996] 2 NZLR 129 (CA) [*Searle*].

5 Unless the action was brought with the consent of the intended defendant before the expiration of six years from that date.

6 *Murray v Morel & Co Ltd* [2007] NZSC 27, [2007] 3 NZLR 721 [*Morel*] at [64] per Tipping J, citing Lord Reid's speech in *Cartledge v E Jopling & Sons Ltd* [1963] AC 758 (HL) at 771–772.

7 *Invercargill City Council v Hamlin* [1996] 1 NZLR 513 (PC) [*Hamlin*].

8 At 526.

9 *Morel*, above n 6, at [42].

reasonable discoverability for accrual purposes not only in relation to damage or loss but also in relation to the causation of that damage or loss.[10] The Court reasoned:[11]

> To hold that a plaintiff who has not discovered that a bodily injury is attributable to the wrongful action of another, and who could not reasonably have discovered that fact, is barred from suit if the injury in fact occurred outside the statutory period is effectively to deny a person the right of action. We do not see that consequence as being required by the legislation. We would therefore hold that for the purposes of s 4(7) of the Limitation Act 1950, a cause of action accrues when bodily injury of the kind complained of was discovered or was reasonably discoverable as having been caused by the acts or omissions of the defendant.

[7] Subsequently in *Murray v Morel & Co Ltd* a majority of the Supreme Court held that there is no general principle that a cause of action does not accrue for limitation purposes until the elements are reasonably discoverable by the plaintiff.[12] As Tipping J explained:[13]

> [69] In my view the numerous references in the Limitation Act to accrual of a cause of action can only be construed as references to the point of time at which everything has happened entitling the plaintiff to the judgment of the Court on the cause of action asserted. Save when the Limitation Act itself makes knowledge or reasonable discoverability relevant, the plaintiff's state of knowledge has no bearing on limitation issues. Accrual is an occurrence-based, not a knowledge-based, concept. The Limitation Act as a whole is structured around that fundamental starting point. …

[8] For Roche NZ Mr MacGillivray contended that the reasoning in *Morel* undermines *Searle* which should not be followed or applied simply because it is a longstanding authority. He submitted that this Court in *White v Attorney General* had held that *Searle* now needs to be considered in light of *Morel.*[14]

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10 At [57].

11 *Searle*, above n 4, at 132–133.

12 The recognition of a general doctrine of reasonable discoverability was viewed as properly a matter for Parliament: see *Morel*, above n 6, at [2] per Blanchard J and [74]–[76] per Tipping J.

13 Earlier at [63] Tipping J noted the Privy Council's recognition of *Hamlin* as a case where the element of knowledge or discoverability can properly be regarded as forming a part of the cause of action itself.

14 *White v Attorney-General* [2010] NZCA 139 at [93].

[9] However that submission fails to recognise that in *Morel* the Supreme Court explicitly addressed what Tipping J described as the "status" of *Searle*:[15]

> [82] If discoverability issues can, as in *Hamlin*, be regarded as an ingredient of the cause of action itself, rather than being a facet of when time starts to run, they can properly be brought to account without doing violence to the structure, language and purpose of the Limitation Act. In this case it is not necessary to reach any final conclusion whether the circumstances of *Searle* and like cases can properly be analysed along those lines. Nor would it be appropriate in this case to come to any final conclusion whether *Searle* was wrongly decided. All that can be said is that the reasoning employed in it is difficult to reconcile with the general views I have expressed about the place of reasonable discoverability in the limitation field. That is not to say, however, that the actual result in *Searle* might not be capable of justification on a different process of reasoning.

[10] Blanchard J considered that *Searle* and *S v G* should not be overruled, and was not comfortable with an attempt to distinguish or "ring-fence" those cases solely on logical grounds. He explained:

> [4] … In cases of those kinds, these decisions of the Court of Appeal have been understood for over a decade to state the law of New Zealand. Undoubtedly, they have been relied upon. It is not without moment that Parliament has reformulated the accident compensation scheme in the Injury Prevention, Rehabilitation, and Compensation Act 2001, and relevantly amended it in 2005, so that it now provides cover for persons in the position of the plaintiffs in *S v G* (in s 21A) and in *Searle* (in s 20(2), read with s 32), thereby limiting the practical application of those cases for the future. But there has been no legislative overruling of the Court of Appeal's interpretation of the Limitation Act.
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> (Footnote omitted.)

Mindful of the limited number of plaintiffs who might rely on those decisions,[16] he preferred not to produce an injustice by overturning them.[17]

[11] We do not consider that it is appropriate to entertain Mr MacGillivray's invitation to overrule *Searle*. The Supreme Court was afforded the opportunity in

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15 And also of *S v G* [1995] 3 NZLR 681 (CA). In *S v G* the plaintiff claimed exemplary damages for personal injury resulting from sexual abuse, and said she only became aware of the link between the abuse and her psychological problems some ten years later. The Court adopted the reasonable discoverability test in relation to the causative link between the sexual abuse alleged and the psychological harm relied on.

16 Consequent upon the extension of statutory cover.

17 *Morel*, above n 6, at [5].

Morel to overrule *Searle*, but declined to do so.[18] Blanchard J explained why in his view it would not be appropriate to overturn *Searle*. His reasons, though strictly speaking obiter, are highly persuasive. We agree with his analysis.

[12] There is a further reason for our declining to reconsider *Searle*. It follows from Blanchard J's observation concerning the absence at that time of any legislative overruling of *Searle*. Subsequently when the 1950 Act was repealed by the Limitation Act 2010 (the 2010 Act), Parliament was presented with the opportunity to address this anomaly. However s 59 relating to causes of action based on acts or omissions prior to 1 January 2011 relevantly provided:

> (2) The action, cause of action, or right of action must, despite the repeal of the Limitation Act 1950 and unless the parties agree otherwise, be dealt with or continue to be dealt with in accordance with the Limitation Act 1950 as in force at the time of its repeal.

[13] While mindful of the reservations that have been expressed about the notion of legislative endorsement,[19] and recognising the possible lack of legislative appetite to revisit principles solely in the context of a transitional provision, we nevertheless consider that Parliament can be expected to have been cognisant of the then recent *Morel* decision in stating that the extant law should continue to apply. For this further reason we do not consider that *Searle* should be revisited in cases to which the transitional provision in the 2010 Act applies.

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18 The Judges reached this result by different paths. As noted above, Blanchard J considered that the courts should not revisit *Searle* regardless of whether it could be distinguished or "ring-fenced", as to do so could produce an injustice for some plaintiffs (at [4]–[5]). Tipping J said it was not appropriate to come to any final conclusion on whether *Searle* was wrongly decided, but left open the possibility that a future court might need to consider that issue (at [82]). McGrath J considered that *Searle* was not undermined by the reasoning in *Hamlin*, and was in any event distinguishable (at [100]–[102]). Gault J (dissenting on the limitation issue) considered that *Searle* was correctly decided and only the legislature could overrule the decision, and that a general principle of reasonable discoverability should be adopted (at [114]–[117]). Henry J did not consider that it was necessary to review *Searle* in any detail as the decision did not establish any general principle and was distinguishable. Rejecting any general principle of reasonable discoverability did not require *Searle* to be overruled (at [148]). A majority of the judges (Tipping, McGrath and Henry JJ) proceeded on the basis that *Searle* was distinguishable: it follows that the various (conflicting) observations made about its status cannot be seen as forming part of the ratio decidendi of the Supreme Court decision.

19 Discussed in Ross Carter *Burrows and Carter Statute Law in New Zealand* (5th ed, LexisNexis, Wellington, 2015) at 211–214.

[14] If *Searle* survived Mr MacGillivray advanced an alternative submission that it ought not to be applied to the instant case which, unlike *Searle*, cannot be categorised as one where it was impossible or nearly impossible to discover the connection between the injury and the breach of duty. The point was made that Mr Austin's medical records would have revealed that he had taken Roaccutane since 1985 and had sought on-going treatment for spinal problems from 1993. However published medical studies[20] were said to establish that skeletal abnormalities were a known risk associated with taking Isotretinoin[21] at high doses for extended periods of time.

[15] Mr MacGillivray argued that to postpone the running of time in the present case would in effect be to hold that a cause of action did not and could not accrue until the claimant had personally discovered a link between Roaccutane and his ailments. That would represent an unwarranted extension of the principle of reasonable discoverability.

[16] Consideration of that contention would necessitate a review of the evidence and making factual findings. That is the function of a trial and it is not appropriate in the context of a strike out application. On this particular aspect we agree with the approach of the Associate Judge in his reasons for declining the application.

[17] In view of our conclusions on issue 2 it is unnecessary for us to engage with the issue of postponement of the running of time in respect of Mr Austin's cause of action under s 28 of the 1950 Act.[22]

Should the compensatory damages claim be struck out?

[18] The Act provides entitlements only to those who suffer personal injury or death (or to their dependents) who are covered under the Act or former legislation. As Ms Hansen for the Corporation submitted, the quid pro quo of statutory cover is that victims of personal injury relinquished the right to sue for compensatory damages arising out of that personal injury at common law. In instances where there is no cover

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20 Dating from 1983 to 1990.

21 The medical name for Roaccutane.

22 Section 28 of the Limitation Act 1950 provides for the postponement of the limitation period in cases of fraud or mistake.

available for personal injury or death, there can be no entitlements under the Act and there is no bar to bringing a claim for compensatory damages.

[19] On 29 March 2015 Mr Austin's dermatologist made a treatment injury claim on Mr Austin's behalf for DISH of his cervical spine. The treatment said to give rise to the injury was the Roaccutane prescribed in the mid-1980s and 1990s for acne. On 11 December 2015 the Corporation accepted the claim and granted cover for DISH. However it did not grant cover for Mr Austin's spondylosis which it concluded was a degenerative condition and not caused by treatment.[23] Mr Austin received entitlements including weekly compensation for a period of nearly two years in the sum of approximately $135,000.

[20] The Associate Judge considered that Mr Austin should not be denied the opportunity to argue that the injuries he sustained did not fall within the provisions of the Act but rather that what he suffered was an ordinary consequence of the consumption of Roaccutane.[24] Challenging that conclusion, Mr MacGillivray submitted that it is an abuse of process for Mr Austin as the grantee of cover and the willing recipient of financial entitlements under the Act to be heard to argue that his injuries were not treatment injuries in order to pursue a claim for compensatory damages. Similarly he was critical of Mr Austin's decision to "hedge his bets" by retaining those entitlements while pursuing his damages claim.

[21] While maintaining the contention that Mr Austin had not suffered a "treatment injury", at the hearing in this Court Mr Thwaite for Mr Austin advanced a new argument to the effect that the activities of a supplier of a pharmaceutical are not "treatment". In order to evaluate these arguments a review of the relevant statutory provisions is necessary.

Statutory framework

[22] Under s 20 of the Act cover is provided for personal injuries suffered in New Zealand on or after 1 April 2002 in three principal ways: personal injury caused

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23 Mr Austin unsuccessfully sought to review that aspect of the decision.

24 *Austin v Roche Products (New Zealand) Ltd*, above n 1, at [52]–[53].

by an accident, treatment injury or work-related gradual process, disease or infection. Provision for treatment injury was introduced in 2005[25] replacing the previous sections concerning medical misadventure, medical error and medical mishap.

[23] "Treatment injury" is defined in s 32:

> (1) **Treatment injury** means personal injury that is—
>
> (a) suffered by a person—
>
> (i) seeking treatment from 1 or more registered health professionals; or
>
> (ii) receiving treatment from, or at the direction of, 1 or more registered health professionals; or
>
> (iii) referred to in subsection (7); and
>
> (b) caused by treatment; and
>
> (c) not a necessary part, or ordinary consequence, of the treatment, taking into account all the circumstances of the treatment, including—
>
> (i) the person's underlying health condition at the time of the treatment; and
>
> (ii) the clinical knowledge at the time of the treatment.

[24] "Treatment" is defined in s 33(1) to include:

> (a) the giving of treatment:
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> (b) a diagnosis of a person's medical condition:
>
> (c) a decision on the treatment to be provided (including a decision not to provide treatment):
>
> (d) a failure to provide treatment, or to provide treatment in a timely manner:
>
> …

[25] By the Injury Prevention, Rehabilitation, and Compensation Amendment Act (No 2) 2005.

[25] The surrender of rights to claim compensatory damages by those entitled to cover, which is part of the "social contract"[26] represented by the first accident compensation scheme, is given effect to by s 317:[27]

> **317 Proceedings for personal injury**
>
> (1) No person may bring proceedings independently of this Act, whether under any rule of law or any enactment, in any court in New Zealand, for damages arising directly or indirectly out of—
>
> (a) personal injury covered by this Act; or
>
> (b) personal injury covered by the former Acts.
>
> …

[26] The scope and purpose of the s 317 bar was confirmed by the Supreme Court in *Davies v Police* where the majority reiterated the social contract aspect of the ACC regime and the importance of an effective bar in maintaining the integrity of the scheme.[28] Delivering the majority judgment Elias CJ explained:[29]

> Section 317 is a pivotal provision in the social contract implemented through the accident compensation legislation. It prohibits any proceedings independent of the Act, "whether under any rule of law or any enactment", for damages arising "directly or indirectly out of … personal injury covered by this Act". The prohibition does not extend to damage to property. Section 317(7) makes it clear that it is the scope of the Injury Prevention, Rehabilitation, and Compensation Act that prevents recovery, rather than whether a claimant actually receives any entitlement under the Act.[30] It provides that the prohibition on proceedings under s 317(1) is unaffected by the failure of a person to lodge a claim for personal injury, or by any surrender of rights relating to personal injury, or by the fact that the person who has suffered personal injury "is not entitled to any entitlement under this Act".

As this Court observed in *McGougan v DePuy International Ltd*, fundamental to the social contract is that the statutory bar is coextensive with cover under the Act.[31]

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26 See the purpose provision in s 3 of the Accident Compensation Act 2001, most recently discussed in *McGougan v DePuy International Ltd* [2018] NZCA 91, [2018] 2 NZLR 916.

27 Claims for exemplary damages are unaffected by the Act: s 319.

28 *Davies v Police* [2009] NZSC 47, [2009] 3 NZLR 189.

29 At [27] (footnotes omitted).

30 The Act's name was changed to the Accident Compensation Act 2001 on 3 March 2010: Accident Compensation Amendment Act 2010, s 5(1)(a).

31 *McGougan v DePuy International Ltd*, above n 26, at [32].

[27] With reference to Mr Austin's new argument it is also necessary to note cl 3(1) of sch 1:

> **3 When Corporation is liable to pay or contribute to cost of ancillary services related to treatment**
>
> (1) The Corporation is liable to pay or contribute to the cost of any service if the service facilitates the treatment and the service is reasonably required as an ancillary service related to treatment, such as—
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> (a) accommodation:
>
> (b) escort for transport for treatment:
>
> (c) pharmaceuticals prescribed by a treatment provider who has statutory authority to prescribe pharmaceuticals:
>
> (d) laboratory tests requested by a registered health professional:
>
> (e) transport (whether emergency or otherwise).

An ordinary consequence of treatment?

[28] Mr Austin's second amended statement of claim asserted that a claim for non-exemplary damages in respect to an ailment is not barred by s 317 to the extent that such ailment is not a "treatment injury" in terms of ss 20(2) and 32(1)(c). Roche NZ's request for further particulars sought the identification of Mr Austin's alleged ailments or medical problems caused by his taking Roaccutane and the basis on which they were contended not to be a treatment injury. Mr Austin's reply stated that no response was required.

[29] However, as in the High Court, Mr Austin's argument, that his DISH diagnosis was not a treatment injury the subject of cover under the Act, was based on the contention that his injury was an ordinary consequence of treatment with Roaccutane. Hence the third element in the definition of treatment injury as set out in s 32(1)(c) was not satisfied.

[30] Mr Thwaite submitted that sufficient evidence exists that Mr Austin's DISH ailment was "inherent" in Roaccutane. As he expressed it:

> Just like a poison, which will ordinarily produce a predictable result. Hence the ailments are not 'accidental', but an *ordinary consequence* of the

> treatment with Roaccutane. The ailments do not need to be the [sole] ordinary consequence.

He distinguished *McGougan v DePuy International Ltd* on the basis that in that case an entitlement to cover under the Act was conceded whereas Mr Austin had put coverage in issue.

[31] The structure of s 32(1) provides for the presence of two elements followed by a carve out excluding two categories of personal injury, namely:

- personal injury that is not a necessary part of the treatment; and
- personal injury that is not an ordinary consequence of the treatment.

The former contemplates a personal injury suffered in the course of the treatment whereas the latter appears to envisage a personal injury which is an effect or outcome of the treatment. As the Explanatory Note to the 2005 Bill stated, treatment injury would not cover injuries that were an anticipated part or consequence of the treatment, such as a surgical incision during an operation.[32] Either circumstance is sufficient to take an injury outside that for which cover would be provided.[33]

[32] The second exclusion, the focus of argument in this case, contemplates outcomes or effects of two types: ordinary or non-ordinary. However both instances will be the consequence of the treatment. In order for a product, like a pharmaceutical, to have a consequence, there must be some aspect of the pharmaceutical that causes or contributes to the personal injury. In that sense the defect or operative cause can be said to be inherent in the product. But we do not find Mr Thwaite's proposition that the outcome was "inherent" in the pharmaceutical advances the analysis as to the meaning of the adjective in the phrase "ordinary consequence".

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[32] Injury Prevention, Rehabilitation and Compensation Amendment Bill (No 3) 2004 (165-1) (explanatory note) at 4.

[33] *Accident Compensation Corporation v McEnteer* HC Wellington CIV-2008-485-1800, 1 December 2008 at [21]. That point was not in issue on appeal in *McEnteer v Accident Compensation Corporation* [2010] NZCA 126, [2010] NZAR 301.

[33] The meaning of the phrase "ordinary consequence" in s 32 will need to be considered by this Court in another appeal due to be heard in 2020.[34] However we do not consider that the present case raises any significant issues about the boundaries of that concept. The adjective "ordinary" is commonly defined to mean regular or usual.[35] Likewise the adverb "ordinarily", which features in a variety of statutory expressions, means in an ordinary or unexceptional way. Similarly the phrase "out of the ordinary" means unusual.

[34] The context of the usage here is the "not [an] ordinary consequence of the treatment". We consider that whatever the boundaries of that phrase may be, it is clearly intended to exclude unexpected and significantly adverse medical outcomes which are disproportionate to the purpose of the treatment and the benefit expected to be derived from it.

[35] The DISH injury which Mr Austin suffered as a consequence of his treatment with Roaccutane was such an outcome. Hence it was not an ordinary consequence of his treatment. It follows that the requirement in s 32(1)(c) was satisfied and his injury qualified as a treatment injury. He was entitled to cover and hence his claim for compensatory damages in respect of his DISH injury was barred by s 317(1).[36]

[36] Mr Thwaite advanced a further argument to the effect that the social contract is not intended to extend to manufacturers or distributors of defective medicines. He drew attention to the fact that s 32(4) provides that treatment injury includes personal injury suffered by a person as a result of treatment given as part of a clinical trial in two circumstances. The first is where a claimant did not consent in writing to participate.[37] Mr Thwaite's focus was the second specified in s 32(6):

> (6) The other circumstance referred to in subsection (4) is where—
>
> (a) an ethics committee—
>
> (i) approved the trial; and

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34 The appeal is from *Accident Compensation Corporation v Ng* [2018] NZHC 2848.

35 *Shorter Oxford English Dictionary* (6th ed, Oxford University Press, Oxford, 2007) vol 2 at 2021.

36 Ms Hansen for the Corporation accepted that to the extent Mr Austin sought to claim compensatory damages for any injury not covered by the Act, eg spondylosis, s 317 did not preclude such a claim.

37 Accident Compensation Act, s 32(5).

(ii) was satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled; and

(b) the ethics committee was approved by the Health Research Council of New Zealand or the Director-General of Health at the time it gave its approval.

[37] In view of the requirement in s 32(6)(a)(ii) he submitted that there would not be cover, and hence the s 317 bar would not apply, where that would protect a manufacturer or distributor who gained the principal benefit of a clinical trial. Hence he submitted that "not [an] ordinary consequence" in s 32(1)(c) should be interpreted so as to exclude a bar to claims made against manufacturers or distributors when to do otherwise would impose a burden on the people of New Zealand in the form of rehabilitation costs.

[38] The early history of the provision of cover for the treatment of injuries sustained in clinical trials was explored in detail by Nicola Peart and Andrew Moore in "Compensation for Injuries Suffered by Participants in Commercially Sponsored Clinical Trials in New Zealand".[38] In brief, under the Accident Compensation Act 1972 the concept of personal injury by accident included medical misadventure which covered participants harmed in clinical trials.[39] However the Accident Rehabilitation and Compensation Insurance Act 1992 excluded from the definition of medical misadventure an injury sustained in a clinical trial in which the injured person agreed in writing to participate.[40]

[39] Peart and Moore explained:[41]

> The exclusion of clinical trials had a profound effect on all clinical research in New Zealand. Some researchers were forced to terminate their trials immediately, while others managed to obtain insurance cover at considerable and unexpected expense. Public pressure persuaded Parliament to amend the Act in 1993 with retrospective effect, but only with respect to certain clinical trials.

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38 Nicola Peart and Andrew Moore "Compensation for Injuries Suffered by Participants in Commercially Sponsored Clinical Trials in New Zealand" (1997) 5 Med L Rev 1.

39 *Green v Matheson* [1989] 3 NZLR 564 (CA).

40 Accident Rehabilitation and Compensation Insurance Act 1992, s 5(8).

41 Peart and Moore, above n 38, at 3–4 (footnotes omitted).

[40] An amendment in 1993[42] narrowed the exclusion to the form which was reproduced in the original s 32 of the current Act (addressing medical misadventure) and is now repeated in substance in the current s 32(5) and (6).

[41] We consider that there is force in the suggestion in *Health Law in New Zealand* that the underlying policy of the exclusion was that since a commercial sponsor derives the financial benefit from the clinical trial, rather than the State, that sponsor should bear the cost of compensating participants injured in the trial.[43] That is the extent of the exclusion. There is nothing in the text of the exclusion or in the underlying history that suggests any broader interpretation is required. Mr Austin did not take Roaccutane as part of a clinical trial and hence s 32(6) has no application to him.

[42] There is simply no basis in our view for the extravagant extrapolation advanced by Mr Thwaite that, because some clinical trials involve pharmaceutical products, the Act should be read as excluding from treatment (and hence cover) the administration by a medical practitioner to a patient of any pharmaceutical medicine. Consequently there was no justification for attributing to the second exclusion in s 32(1)(c) the extended meaning which Mr Thwaite advocates. To do so would be inconsistent with the approach that a generous interpretation should be accorded to the scope of the term "personal injury".[44]

[43] A slightly less ambitious version of this argument, that Mr Thwaite also appeared to be advancing, was that the supply of pharmaceuticals by a manufacturer is not itself "treatment" and manufacturers are not protected by the bar, even if the supply of those pharmaceuticals by a medical practitioner to a patient itself amounts to "treatment". The difficulty with this variant of the argument is that if the supply of pharmaceutical products to a patient is "treatment" for the purposes of the Act, and if a treatment injury results for which there is cover, the statutory bar in s 317 prevents any proceedings being brought against any person in respect of that injury. It is impossible to read s 317 as preserving rights of action in respect of the injury against

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42 Accident Rehabilitation and Compensation Insurance Amendment Act (No 2) 1993, s 3.

43 Peter Skegg and Ron Paterson (eds) *Health Law in New Zealand* (Thomson Reuters, Wellington, 2015) at [31.6.1].

44 *Harrild v Director of Proceedings* [2003] 3 NZLR 289 (CA) at [19] per Elias CJ, [39] per Keith J and [130] per McGrath J.

some categories of defendant, but not others. There is nothing in the text of the Act to support that interpretation, and it is inconsistent with the purpose of the Act and the social contract to which it gives effect.

Provision of Roaccutane: services, not treatment

[44] At the hearing Mr Thwaite advanced a new argument based on the proposition that the supply of Roaccutane was not a "treatment" as defined in s 33 but instead the provision of a "service". Consequently his ailment which derived from his consumption of Roaccutane was not caused by treatment, as s 32(1)(b) requires, and therefore he did not suffer a treatment injury. This submission drew on the following points:

- cl 3(1) of sch 1 distinguishes between a treatment and a service facilitating the treatment, such services including "pharmaceuticals prescribed by a treatment provider who has statutory authority to prescribe pharmaceuticals";

- a treatment provider is defined in s 6(1) to embrace a variety of medical operational groups but does not include a supplier of pharmaceuticals;[45] and

- the definition of "treatment" in s 33 does not cover the activities of a supplier of pharmaceuticals.

Reference was again made to the exclusion of liability for certain medical trials in s 32(5) and (6).

[45] In our view it is apparent from s 32 that the "treatment injury" concept is intended to include a personal injury suffered as a consequence of the provision of medication (by whatever medium — oral, topical or injection) to a patient by an appropriately qualified health professional. Section 32(1)(a)(i) and (ii) refer to registered health professionals, the definition of which includes a pharmacist.[46]

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45 See now the Accident Compensation (Definitions) Regulations 2019, reg 8.
46 Regulation 7.

Furthermore it is apparent from s 32(6)(a)(ii) relating to clinical trials that a treatment injury can be caused by a "medicine". That is the only reference in ss 32 and 33 to the physical form of therapy administered in respect of a personal injury. There is no reference in those sections to "pharmaceuticals".

[46] Consequently we consider that the definition of treatment in s 33, which is inclusive, necessarily incorporates within "the giving of treatment" (s 33(1)(a)) the administration of medicine which has been prescribed consequent upon a diagnosis of a person's medical condition (s 33(1)(b)) by a registered health professional. That conclusion is reinforced by the fact that s 33(1)(f) refers to "the provision of prophylaxis".

[47] A contrary interpretation of the tenor advanced by Mr Thwaite would give rise to an uncertain line of demarcation between diagnosis and "treatment" on the one hand and therapy by the administration of medicines on the other. The availability of statutory cover should not turn on such nice distinctions.

[48] We recognise that the Act contains a number of provisions which refer to "services", notably those relating to service agreements for the purchase of public health acute services and other health services: ss 301 and 302. Those sections, which contain references to "other services (including pharmaceuticals and laboratory services)" address the relationship between the Corporation and treatment providers. In our view several of the provisions in sch 1 (Entitlements) contemplate the same context: for example "cost" is defined in cl 1(2) to mean the cost agreed by the Corporation and the treatment provider.[47] We further note that regulations were made in relation to the costs which the Corporation is liable to pay both in respect of cost of treatment[48] and ancillary services.[49]

[49] We consider that references to pharmaceuticals (and indeed to laboratory tests) in cl 3(1) are to be construed in that context. In our view the manner of description of the Corporation's financial obligations under the Act vis-à-vis treatment providers can

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47 If paragraphs (a) and (b) of cl 1(1) do not apply.

48 Accident Compensation (Liability to Pay or Contribute to Cost of Treatment) Regulations 2003.

49 Accident Compensation (Ancillary Services) Regulations 2002 which address transport, escort, support person and accommodation costs but make no provision for pharmaceuticals.

have no bearing on the interpretation of what constitutes "treatment" by a registered health professional for the purposes of determining the scope of cover for treatment injury under the Act.

[50] Accordingly we consider that the provision of a prescription for self-administration of a pharmaceutical involved giving a treatment (s 33(1)(a)) consequent upon the diagnosis of Mr Austin's DISH condition (s 33(1)(b)) by a registered health professional from whom Mr Austin had sought treatment (s 32(1)(a)(i)). Consequently Mr Austin suffered a treatment injury in respect of which he had cover and entitlements under the Act. Any different interpretation would be artificial and unrealistic. It could have unacceptable limitations for large numbers of New Zealanders who presently look to the Corporation for cover in respect of adverse reactions to prescribed pharmaceuticals.

A qualification

[51] Although Mr Austin took Roaccutane which had been prescribed for him by a number of medical practitioners, it transpired that for a period of some months in around 2000 he also took some Roaccutane that had been prescribed by a doctor to Mr Austin's sons. To the extent, if any, that his consumption of that small amount of Roaccutane caused or contributed to his DISH ailment, it was not a treatment injury because it was not caused by treatment which Mr Austin had sought from a registered health professional.

[52] There may be room for argument therefore that such self-administration of Roaccutane prescribed for other persons did not constitute the giving of treatment and hence did not give rise to a treatment injury which would be the subject of cover. In those circumstances we consider that it is appropriate to reserve leave for Mr Austin to file an amended pleading seeking compensatory damages solely in respect of that conduct, should he wish to do so.

Result

[53] The appeal is allowed in part.

[54] The claim for compensatory damages is struck out.

[55] Leave is reserved for Mr Austin to file an amended pleading seeking compensatory damages in respect of self-administration of Roaccutane (prescribed for other persons) which was not prescribed for him by a registered health professional from whom he sought treatment.

[56] Costs lie where they fall.

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