**IN THE DISTRICT COURT**
**AT AUCKLAND**

**I TE KŌTI-Ā-ROHE**
**KI TĀMAKI MAKAURAU**

**CRI-2022-004-004652**
**[2022] NZDC 22175**

**COMMERCE COMMISSION**
Prosecutor

v

**EGO PHARMACEUTICALS PTY LIMITED**
Defendant

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| Hearing: | 26 October 2022 |
| Appearances: | A McClintock and J Barry for the Commerce Commission<br>J Dixon for the Defendant |
| Judgment: | 25 November 2022 |

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**DECISION OF JUDGE N R DAWSON ON SENTENCING**

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## Introduction – the Charges and the Factual Background

[1] The defendant company, Ego Pharmaceutical Pty Ltd, has pled guilty to two representative charges of making unsubstantiated representations in breach of ss 12A and 40(1) of the Fair Trading Act 1986 (the Act).

[2] The defendant made representations about its products, sunscreens called Sunsense Ultra and Sunsense Invisible (the Products), despite not having reasonable grounds for the representations between 22 February 2019 and 11 June 2020 (the Charge Period).

[3] The charges relate to representations about the Products which claimed that they provided "SPF 50+" and "Very High" protection throughout the charge period (the Representations).

[4] Claims about the SPF (Sun Protection Factor) of sunscreen in New Zealand are governed by AS/NZS 2604:2012 (the Standard). While compliance with the Standard was not mandatory under s 29 of the Act at the time the Representations were made, any claims still needed to comply with ss 9-13 of the Act. As such claims which are made about sunscreens need to comply with the Standard. Under the Standard only products which tested SPF 60 or higher could claim to be SPF 50+ or claim to provide very high protection.

[5] The Representations were a continuation of claims made about both products since the introduction of the Products to New Zealand in 2016 until their withdrawal on 11 June 2020. The grounds on which the defendant made these claims was based upon testing conducted by AMA Laboratories Inc (AMA), a United States of America based testing provider. A retest in March 2018 by AMA was done in response to concerns and showed SPF 60 or higher for the Products. Subsequently, charges were announced relating to the issuing of fraudulent testing certificates by AMA on 9 August 2019 by the US Food and Drug Administration, with the director of AMA having since pled guilty to related charges. The defendants became aware of these charges on an unspecified date later in the month. When the defendant reached out to AMA in January 2020, they refused to provide comment on the accuracy of the testing results regarding the Products upon which the Representations were based.

[6] In addition to the AMA testing there were multiple rounds of independent tests were carried out on the Products. These include:

(a) December 2017, Consumer NZ publishes test results of Sunsense Ultra from an independent Australian laboratory which showed SPF of 17.8-21.1. This prompted the retest by AMA.

(b) October 2018, Consumer NZ results from Dermatest show SPF for Sunsense Invisible 15.98.

(c) Between October 2018-January 2019, the defendant commissioned a Ring Study in response to Consumer NZ's reports and contracted five independent laboratories to carry out testing of Sunsense Ultra. All five laboratories show SPF below 50, with a range of 14.3-44.2. No action was taken over these results.

(d) Consumer NZ tested Sunsense Ultra in November 2019 and published results that it only had an SPF of 25.82.

(e) In December 2019 the Commerce Commision (the Commission) advised the defendant that testing carried out by an independent laboratory indicated Sunsense Ultra had an SPF of 37.5.

[7] The basis of the charges are that the cumulative effect of the testing by independent laboratories meant that by February 2019 the defendant did not have reasonable ground on which to make the claim that the products were "SPF 50+" or that they afforded "very high" protection and as such the Representations were unsubstantiated. Subsequent testing and the revelations about AMA made the grounds increasingly unreasonable.

[8] Despite the testing indicating that the claims could not be substantiated the Defendant continued to make the Representations about the Products until 11 June 2020, about 6 months after AMA refused to provide any assurance as to the validity of their results.

**The Law**

[9] Section 12A of the Act is a prohibition on any person, in trade, from making an unsubstantiated representation. Whether or not a claim is substantiated in not concerned with whether it is true, it merely looks at if the person had reasonable grounds on which to believe a statement was true. The purpose of s 12A is:[1]

[1] *Commerce Commission v Fujitsu General New Zealand Limited* [2017] NZDC 21512 at [22].

> …to ensure that representations about goods, services, or interests in land are made on the basis of sound information or evidence.

[10] A person who makes an unsubstantiated representation is liable under s 40(1) of the Act for a fine of up to $600,000. Parliament specifically chose to have unsubstantiated representations be the same offence as misrepresentations. This means that while this case is a first of its kind and must be decided on its own facts, prior cases under ss 9-13 of the Act can be useful in consideration as to the appropriate sentence.[2]

[11] The position of the Commission is that the defendant failed to properly review new evidence about its claims as they came to light. While the defendant had reasonable grounds initially to make the claim a component of the reasonable grounds is that a trader must not close their eyes to evidence which contradicts their claim. This evidence must be reviewed to ensure that the claims are reasonable. The defendant breached s 12A when they failed to adequately take into account an increasing body of evidence from independent tests which indicated their claims could not be substantiated by sound information or evidence.

[12] The Commissions position is accepted by the defendant. The defendant accepts it made an error in judgement in continuing to accept AMA's claims and by February 2019 did not have reasonable grounds on which to make the claims. It acknowledges its response in November 2019 to cease supply was inadequate as it only facilitated a withdrawal of the Products in July 2020 despite having increasing evidence that they were defective and they bore the unsubstantiated claim.

[13] It is on this basis the defendant pled guilty to the offences.

[14] In determining the sentence the scheme of the Act must be kept in mind. The approach that has been taken was summarised by Miller J in *Commerce Commission v Steel & Tube Holdings Ltd* following a review of lower court decisions:[3]

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[2] At [52].
[3] *Commerce Commission v Steel & Tube Holdings Ltd* [2020] NZCA 549 at [90]-93].

*The cases recognise that sentencing should begin with the objects of the Fair Trading Act, which pursues a trading environment in which consumer interests are protected, businesses compete effectively, and consumers and businesses participate confidently. To those ends it promotes fair conduct in trade and the safety of goods and services and prohibits certain unfair conduct and practices.*

*Customary sentencing methodology applies. Factors affecting seriousness and culpability of the offending may include: the nature of the good or service and the use to which it is put; the importance, falsity and dissemination of the untrue statement; the extent and duration of any trading relying on it; whether the offending was isolated or systematic; the state of mind of any servants or agents whose conduct is attributed to the defendant; the seniority of those people; any compliance systems and culture and the reasons why they failed; any harm done to consumers and other traders; and any commercial gain or benefit to the defendant.*

*Factors affecting the circumstances of the offender include: any past history of infringement; guilty pleas; co-operation with the authorities; any compensation or reparation paid; commitment to future compliance and any steps taken to ensure it. The court may also make some allowance for other tangible consequences of the offending that the defendant may face. By tangible we mean to exclude public opprobrium that is an ordinary consequence of conviction; publicity ordinarily serves sentencing purposes of denunciation and accountability. The defendant's financial resources may justify reducing or increasing the fine. Of course any other sentencing considerations applicable, such as totality and the treatment of like offenders, will also be taken into account.*

*This catalogue of considerations is derived from the legislation and the cases. It is not exhaustive, nor is it mandatory. We offer it for several reasons. It seeks to make clear that the offender's state of mind is just one of a number of culpability factors, albeit important. It treats state of mind as a question of fact and degree. It recognises that the starting point should reflect not only the conduct and state of mind of those employees or agents responsible for the contravention but also their seniority and the existence and effectiveness of any compliance systems and culture, which are usually attributable to senior management. It includes the extent of any commercial gain or benefit and the defendant's size or financial capacity, as one would expect for offending in a commercial setting. Finally, it is organised according to circumstances of the offence and the offender, consistent with modern sentencing methodology.*

[15] This provides a guide as to what factors are important when determining an appropriate sentence.

**Culpability Factors**

*Nature of Goods*

[16] The Products function is protection against UV radiation. This makes them a product with a health/medicinal property as they protect against skin cancer. Further, the atmospheric conditions in New Zealand make it vitally important that New Zealanders have accurate information about these products so that they can ensure they are adequately protected.

*Importance of the Representations*

[17] The Representations are about the effectiveness of the core quality of the product. The SPF value and UV protection of a sunscreen is a central consideration to consumers. Consumers would purchase a product which provided them with adequate protection for any anticipated UV exposure.

[18] The Representations are also of a type where a consumer would not be able to test or effectively judge for themselves. This combined with the assertion that the Product provides an important health benefit makes it vital that consumers be able to trust representations about its effectiveness.

*The Unreasonableness of the Grounds for the Representations*

[19] It is accepted that initially there were reasonable grounds for the Representations when the products were introduced to the New Zealand Market. However, as evidence accumulated as to the fraud committed by AMA along with the accumulation of evidence from the other independent tests these grounds became increasingly unreasonable. Once the fraud was revealed there was no basis on which to make them, further aggravated by AMA refusing to provide any assurance. Thus, as time progressed the offending became more serious.

*Defendant's State of Mind*

[20] There is dispute between the defendant and the Commission as to the defendant's state of mind during the charge period. It is accepted that at no point did the defendant intentionally seek to make unsubstantiated claims and sought out what at the time appeared to be a credible testing company to ensure their products were of sufficient quality and sought a re-evaluation of the results when issues with the Products were raised with them.

[21] As to the state of mind regarding during the offending the Commission's position is that the defendant's actions amounted to at least wilful blindness if not reckless. They failed to follow the guidelines in the Standard on how to evaluate conflicting results regarding sunscreen and continued to rely on AMA's finding even when their fraud had been revealed. The defendant argues that they merely exercised poor judgement. As to the defendant's state of mind during the offending period, this court finds that by February 2019 the defendant was acting in a wilfully blind manner and from August 2019 the defendants' lack of action was reckless.

[22] By February 2019 both the defendant's independent testing and other parties had carried out multiple rounds of testing which indicated that the claims were erroneous. AMA's findings were the statistical outlier with no independent study aligning with their findings. The Defendant ignored all these other findings, including the results of their own Ring Study. This makes their compliance procedures appear more performative than a genuine attempt at re-evaluation. As such they were acting in a manner that was wilfully blind to evidence which contradicted their claims.

[23] In August 2019, with the revelation that AMA had engaged in fraudulent testing practices, this changed. At this point the issues in relation to the reliability of AMA's test results became irrefutable, both due to a wealth of contradictory evidence and the destruction of AMA's credibility as a testing partner. The fact that AMA would not provide any assurance about the validity of their own tests made it plainly reckless to rely on them.

*Harm Caused*

[24] As both parties note the extent of the harm caused is impossible to quantify. The error has exposed consumers to an unnecessary risk of melanoma and the true level of harm cannot be determined. While it cannot be stated with certainty it can be inferred that some people may suffer from melanoma as a result of inadequate UV protection. If persons do contract melanoma, the risk is high as it is an aggressive form of cancer that frequently leads to the death of the person concerned.

[25] In addition to the medical consequences there are the commercial and financial consequences. Consumers would have paid a higher premium for these products believing they provided the advertised protection. This could also contribute to an erosion of trust in the labelling. Also, there is the unfair advantage granted to the Defendant during this period over competitors who ensured that their products met the standards they claimed.

[26] While none of the harm to persons using the Product or commercial competitors can be accurately quantified its existence needs to be acknowledged in the sentence imposed.

*Extent of the Offending*

[27] The charge period is approximately 16 months and during this time the defendants distributed approximately [redacted] of the Products to [redacted]. This generated approximately [redacted] in revenue and profits were calculated at [redacted] during the charge period.

*Deterrence*

[28] While eliminating commercial gain from offending is not necessary, eliminating commercial gain may be necessary in order to deter offending.[4] Profit is a primary motivation of corporations and as such "financial penalties in the

[4] *Commerce Commission v Steel & Tube Holdings Ltd* [2020] NZCA 549 at [95]-[96].

commercial world are generally regarded as an effective means of deterrence".[5] For this reason setting a penalty that has a meaningful deterrent effect is important to achieving the purposes of the Act.

*Acceptance of Guilt*

[29] Their initial unwillingness to accept that they had been misled by AMA aside, the Defendants they have shown an acceptance of their wrongdoing and responsibility. They have co-operated with the investigation and not sought to unduly prolong these matters, pleading guilty at the earliest opportunity. Their involvement in improving practices generally in this area as well as the treatment of the dangers associated with UV exposure indicate there was no desire to cause harm. It is recognised as a genuine acceptance of wrongdoing.

**Sentence**

[30] The principle sentencing factor in this case must that of deterrence. The claims made by the defendant went well beyond advertising puffery. They were claims specifically made to assure users of the Product that it would help protect their health, particularly from melanoma. Such claims should not be made lightly and when evidence indicates that the claims are by a substantial margin incorrect, immediate action should have been taken due to the risk of harm to users of the Products.

[31] There is no similar case that can be referred to in setting a starting point for sentencing. Many cases have been cited for consideration, but none of them directly relate to the inherent health risks of this case.

[32] The maximum sentence is for a fine of $600,000. It is appropriate to enter concurrent sentences on the charges as there was effectively only one course of actions undertaken by the defendant involving the sale of two very similar products.

[33] It is submitted by both the Commission and the defendant that an appropriate starting point would be a fine of $400,000. A discount of 15% could be allowed for a

[5] *Commerce Commission v GO Healthy New Zealand Limited* [2019] NZDC 25295 at [30].

lack of previous convictions and a further 25% for the guilty pleas and cooperation in the investigation of these charges. That would result in a fine of $240,000.

[34] It is accepted that the submissions by the parties are responsible and useful in setting a sentence for these charges. Notwithstanding the submissions made, the discount for the defendant not having previous convictions is in my view too high. The defendant should have acted sooner once the evidence in the many independent reports came available and been more active in removing the Products from the market. The only action the defendant took was to stop supplying more of the Products to the market. The Products already suppled continued to be sold. In addition, there is no evidence of them taking any action to warn consumers of the Products deficiencies. A warning to consumers should be expected when the Products did not have the health benefits claimed. A discount for not having a previous conviction should be reduced when there has been a tardy and insufficient response, particularly when the health of consumers is put at risk.

[35] This court adopts the submissions of counsel for both parties except for the discount for not having previous convictions. A starting point of $400,000 is adopted. A discount of 25% is allowed for the early guilty pleas and cooperation, but only 5% is allowed as a discount for no previous convictions. The defendant is fined $280,000 concurrent on both charges.

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Judge NR Dawson
District Court Judge | Kaiwhakawā o te Kōti ā-Rohe
Date of authentication | Rā motuhēhēnga: 25/11/2022