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Details of Filing

Document Lodged:	Concise Statement
File Number:	VID540/2021
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH v ENVIRO TECH HOLDINGS PTY LTD & ORS
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 22/09/2021 11:21:31 AM AEST Registrar

Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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CONCISE STATEMENT

FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: VICTORIA
DIVISION: GENERAL **NO VID OF 2021**

SECRETARY OF THE DEPARTMENT OF HEALTH
Applicant

ENVIRO TECH HOLDINGS PTY LTD (ACN 158 508 000)
and others named in the Schedule
Respondents

A. KEY FACTS GIVING RISE TO THE CLAIM

1. The First Respondent, Enviro Tech Holdings Pty Ltd (ACN 158 508 000) (**Enviro Tech**), is a corporation with its registered office in Victoria, Australia.

2. The Second Respondent, Connie Triantos, is the sole director, sole shareholder, and company secretary of the First Respondent.

3. The Third Respondent, Jerry Triantos, is an executive officer of the First Respondent and holds the position of 'Chief of Global Operations'. From at least April 2020, the Third Respondent regularly communicated with the Therapeutic Goods Administration (**TGA**), which is part of the Department of Health, on behalf of the First Respondent.

4. The *Therapeutic Goods Act 1989* (Cth) (**TG Act**) imposes certain requirements in relation to the importation and supply of 'medical devices' in Australia.

5. Section 41BD(1)(ab) of the TG Act, by operation of s 5 of the *Therapeutic Goods (Medical Devices – Specified Articles) Instrument 2020* (Cth) (the **Medical Devices Instrument**), provides that 'medical devices' include 'non-sterile personal protective equipment … intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of transmission of disease between persons'.

6. On 22 March 2020, a delegate of the Minister for Health made the *Therapeutic Goods (Medical Devices – Face Masks and Other Articles) (COVID-19 Emergency) Exemption 2020* (Cth) (the **Exemption**) under s 41GS of the TG Act. The Exemption commenced on 22 March 2020, and remained in force until 31 January 2021.

7. The Exemption applied to 'relevant kinds of medical devices' including 'medical devices that are disposable face masks … designed to be worn by individuals to prevent the

Filed on behalf of the Applicant, Secretary of the Department of Health
File ref: 21003697

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transmission of organisms' (ss 4 and 5).

8. By s 5 of the Exemption, relevant kinds of medical devices were exempt from certain requirements imposed by the TG Act, including the operation of Part 4-5 of the TG Act, concerning the inclusion of medical devices in the Australian Register of Goods maintained under s 9A of the TG Act (the **Register**). Under s 41GS(5) of the TG Act, the Exemption did not apply to medical devices included in the Register.

9. The Exemption was subject to the conditions in s 6. Section 6(a) of the Exemption provided that the Exemption was subject to a condition (the **Condition**) that:

> the relevant kinds of medical devices must only be imported, exported, manufactured or supplied by a person under a contract between the person and the Australian Government Department of Health, or another agency of the Commonwealth acting on behalf of the Australian Government Department of Health, for that purpose…

10. The Exemption included a 'Note 1' that 'there are offences and civil penalty provisions related to the breach of a condition: see Division 3A of Part 4-11 of the Act'.

11. On or about 11 August 2020, the First Respondent imported into Australia, from the People's Republic of China, 500,000 disposable medical face masks branded 'Kombang Disposable Medical Mask', the packaging of which indicated that they were manufactured in Guangzhou (the **Devices**). The packaging of the Devices also contained statements to the effect that:

    11.1. each Device was a 'Disposable Medical Mask', with 'Applicable Scenarios' for use including 'Medical Facilities';

    11.2. the Devices were 'Epidemic Emergency Products'; and

    11.3. each mask 'Effectively blocks the spray of viral droplets' and 'Prevents inhalation of harmful viral droplets'.

12. The Devices were not, at any time on or before 11 August 2020, included in the Register.

13. By reason of the matters alleged in paragraphs 5 to 12 above, the Devices were:

    13.1. 'non-sterile personal protective equipment … intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of transmission of disease between persons', and therefore medical devices within the meaning of s 41BD(1)(ab) of the TG Act, by operation of s 5 of the Medical Devices Instrument;

    13.2. disposable face masks intended to be used to prevent the transmission of organisms; and

    13.3. relevant kinds of medical devices to which the Exemption applied.

14. There was not, at any time on or before 11 August 2020, a contract between the First Respondent (or any other person) and the Australian Government Department of

Health (the **Department**), or another agency of the Commonwealth acting on behalf of the Department, for the supply of the Devices, and the Devices were not imported under such a contract.

15. By importing the Devices into Australia without a contract between the First Respondent and the Department, or another agency of the Commonwealth acting on behalf of the Department, the First Respondent:

    15.1. did an act in relation to a kind of medical device covered by the Exemption that resulted in a breach of the Condition; and

    15.2. contravened s 41MNC of the TG Act.

16. The Second Respondent aided, abetted, counselled or procured the First Respondent's contravention of s 41MNC of the TG Act, including by:

    16.1. carrying out her duties as the sole director, sole shareholder and company secretary of the First Respondent; and

    16.2. making arrangements for the importation of the Devices.

17. The Third Respondent aided, abetted, counselled or procured the First Respondent's contravention of s 41MNC of the TG Act, including by:

    17.1. carrying out his duties as an executive officer of the First Respondent;

    17.2. making arrangements for the importation of the Devices; and

    17.3. making arrangements with the manufacturer of the Devices on behalf of the First Respondent prior to the importation.

18. At the time of engaging in the conduct alleged in paragraphs 16 and 17 respectively, the Second Respondent and Third Respondent were aware (including by reason of the conduct alleged in paragraphs 16 and 17) that:

    18.1. the Devices were non-sterile personal protective equipment intended to be used for the prevention of transmission of disease between persons;

    18.2. the Devices were disposable face masks designed to be worn by individuals to prevent the transmission of organisms;

    18.3. the Devices were or would be imported into Australia by the First Respondent;

    18.4. there was no contract between the First Respondent (or any other person) and the Department, or another agency of the Commonwealth acting on behalf of the Department, in relation to the importation of the Devices.

SUMMARY OF RELIEF SOUGHT FROM THE COURT

19. The Applicant seeks against the Respondents the relief set out in the Originating

Application, comprising:

19.1. declarations under s 21 of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**) that:

19.1.1. the First Respondent has contravened s 41MNC of the TG Act;

19.1.2. the Second Respondent has contravened s 42YC of the TG Act; and

19.1.3. the Third Respondent has contravened s 42YC of the TG Act.

19.2. orders for pecuniary penalties under s 42Y of the TG Act for:

19.2.1. the First Respondent's contravention of s 41MNC of the TG Act;

19.2.2. the Second Respondent's contravention of s 42YC of the TG Act; and

19.2.3. the Third Respondent's contravention of s 42YC of the TG Act.

19.3. orders under s 42YN of the TG Act and s 43 of the FCA Act restraining the Respondents from importing, exporting, supplying or manufacturing medical devices.

19.4. costs under s 43 of the FCA Act.

B. PRIMARY LEGAL GROUNDS FOR RELIEF SOUGHT

20. By the conduct described in paragraphs 6 to 15 above, the First Respondent contravened s 41MNC of the TG Act.

21. By the conduct described in paragraphs 6 to 16 and 18, the Second Respondent contravened s 42YC of the TG Act.

22. By the conduct described in paragraphs 6 to 15 and 17 to 18, the Third Respondent contravened s 42YC of the TG Act.

C. ALLEGED HARM

23. The TG Act includes a range of provisions that are intended to impose controls to promote the safety, suitability for their intended purpose, and quality of medical devices imported into, exported from, or manufactured or supplied in Australia. These include:

23.1. a requirement that medical devices must comply with the 'essential principles' for medical devices, as set out in Schedule 1 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth);

23.2. a requirement that relevant 'conformity assessment procedures' be applied to medical devices, being procedures directed to ensuring the quality of such devices; and

23.3. a process for including medical devices in the Register if they comply with the essential principles and conformity assessment procedures.

24. The Exemption was made in order to allow the importation of personal protective equipment (**PPE**) into Australia for inclusion in the National Medical Stockpile maintained by the Department (**NMS**), in order to deal with the emergency created by the COVID-19 pandemic and related shortfalls in the availability of PPE in Australia. The Exemption removed the controls outlined in paragraph 23 above in order to facilitate the supply of the relevant kinds of medical devices during the COVID-19 pandemic through the NMS. The only controls to which those medical devices were subject, at the time they were imported, were the conditions of the Exemption.

25. As the Devices were covered by the Exemption but were not imported in accordance with the Condition, being the requirement that the Devices be imported under a contract between the importer and the Department (or a Commonwealth agency acting on behalf of the Department), the Devices were not imported in circumstances that would result in their inclusion in the NMS. Consequently, the importation of the Devices had the effect of undermining the Department's efforts to build the NMS and ensure adequate supplies of PPE in Australia during the COVID-19 pandemic.

26. In addition, as the Exemption removed the controls outlined in paragraph 23, it removed the checks in place to ensure that covered medical devices were of appropriate quality and safety and were suitable for their intended purpose. The Condition addressed this scenario by limiting the kinds of medical devices that could be imported to circumstances in which Department or the agency acting on its behalf would necessarily maintain a high degree of oversight.

27. Because the Devices were not imported in accordance with the Condition, the Department did not have oversight over their importation, so it was not known whether the Devices were of appropriate quality and safety and were suitable for their intended purpose. This is of considerable concern given the use of PPE by persons to prevent the transmission of the SARS-CoV-2 virus in the context of the COVID-19 pandemic.

CERTIFICATE OF LAWYER

I Matthew Garey certify to the Court that, in relation to the concise statement filed on behalf of the Plaintiff, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 22 September 2021

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Matthew GareyAGS lawyer
for and on behalf of the Australian Government Solicitor
Solicitor for the Applicant

Schedule

FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: VICTORIA
DIVISION: GENERAL **No QUD of 2021**

Respondents

Second Respondent	Connie Triantos
Third Respondent	Jerry Triantos

Date: 22 September 2021