

NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 21/08/2020 9:50:56 AM AEST and has been accepted for filing under the Court's Rules. Filing and hearing details follow and important additional information about these are set out below.

Filing and Hearing Details

Document Lodged:	Originating Application - Form 15 - Rule 8.01(1)
File Number:	VID558/2020
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH v OXYMED AUSTRALIA PTY LTD & ANOR
Registry:	VICTORIA REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	Interlocutory Hearing
Time and date for hearing:	24/08/2020, 11:00 AM
Place:	Please check Daily Court List for details



Dated: 21/08/2020 2:07:09 PM AEST

A handwritten signature in blue ink that reads 'Sia Lagos'.

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.

The Reason for Listing shown above is descriptive and does not limit the issues that might be dealt with, or the orders that might be made, at the hearing.

The date and time of lodgment also shown above are the date and time that the document was received by the Court. Under the Court's Rules the date of filing of the document is the day it was lodged (if that is a business day for the Registry which accepts it and the document was received by 4.30 pm local time at that Registry) or otherwise the next working day for that Registry.



Form 15
Rules 8.01(1), 8.04(1)

ORIGINATING APPLICATION

FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: Victoria
DIVISION: GENERAL

NO VID OF 2020

SECRETARY OF THE DEPARTMENT OF HEALTH
Applicant

OXYMED AUSTRALIA PTY LTD
First Respondent

MALCOLM HOOPER
Second Respondent

To the Respondents

The Applicant applies for the relief set out in this application.

The Court will hear this application, or make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence.

You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

TIME AND DATE FOR HEARING:

PLACE: Federal Court of Australia
Owen Dixon Commonwealth Law Courts Building
305 William Street
Melbourne VIC 3000

The Court ordered that the time for serving this application be abridged to:

Date:

.....
Signed by an officer acting with
the authority of the District Registrar

Filed on behalf of the Applicant, Secretary of the Department
of Health

File ref: 20203949

Prepared by: Glenn Owbridge
AGS lawyer within the meaning of s 55I of the *Judiciary Act*
1903

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Australia Government Solicitor
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DETAILS OF CLAIM

On the grounds stated in the statement of claim, accompanying affidavit or other document prescribed by the rules the Applicant claims:

1. Declarations under s 21 of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**) that, from and on each day between 20 February 2020 to present, or as otherwise specified:

Advertising goods not included in the Australian Register of Therapeutic Goods

- 1.1. the First Respondent, by advertising devices intended to administer hyperbaric oxygen therapy (**HBOT Devices**) on its website at www.oxymed.com.au (the **Website**), in circumstances where s 42DLB(9) of the *Therapeutic Goods Act 1989* (Cth) applies because the advertisement referred to HBOT Devices that are:

- 1.1.1. “medical devices” as defined in s 41BD of the TG Act ;
- 1.1.2. “therapeutic goods” within the meaning of s 3 of the TG Act;
- 1.1.3. not entered in the Australian Register of Therapeutic Goods maintained by the Applicant under section 9A of the TG Act (the **Register**); and
- 1.1.4. not the subject of an exemption, approval or authority under the TG Act nor an exemption, approval or authority under regulations under the TG Act within the meaning of r 7(i) of the *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**);

in respect of each advertisement, contravened s 42DLB(1) of the TG Act.

- 1.2. the Second Respondent, by causing the First Respondent to advertise each of the HBOT Devices on the Website, in the circumstances outlined in paragraphs 1.1.1 to 1.1.4 above, contravened s 42DLB(1) of the TG Act.
- 1.3. further, or in the alternative to the declaration sought in paragraph 1.2, the Second Respondent aided, abetted, counselled or procured the First Respondent’s contraventions of s 42DLB(1) of the TG Act referred to in the declaration sought in paragraph 1.1 and was therefore involved in those contraventions for the purposes of s 42YC of the TG Act.

Restricted representations

- 1.4. the First Respondent, by advertising, or causing to be advertised HBOT Devices, on the Website in a manner that contained representations that referred to the diseases, conditions, ailments or defects listed in Annexure A hereto, and in circumstances where s 42DLB(4) of the TG Act applies because:



- 1.4.1. each representation in respect of each of the said diseases, conditions, ailments or defects is, by s 28 of the *Therapeutic Goods Advertising Code (No. 2) 2018 (TG Code)*, a restricted representation within the meaning of s 42DD of the TG Act;
- 1.4.2. no approval under s 42DF of the TG Act was in force in respect of any of the restricted representations; and
- 1.4.3. no permission under s 42DK of the TG Act was in force in respect of any of the restricted representations,

in respect of each advertisement, contravened s 42DLB(1) of the TG Act.

- 1.5. the Second Respondent, by causing the First Respondent to advertise HBOT Devices on the Website in the manner and circumstances outlined in paragraph 1.4, contravened s 42DLB(1) of the TG Act.
- 1.6. further, or in the alternative to the declaration sought in paragraph 1.5, the Second Respondent aided, abetted, counselled or procured the First Respondent's contraventions of s 42DLB(1) of the TG Act referred to in the declaration sought in paragraph 1.4 and was therefore involved in those contraventions for the purposes of s 42YC of the TG Act.

Prohibited representations

- 1.7. on each day between 20 February 2020 and 19 June 2020, the First Respondent, by advertising or causing to be advertised HBOT Devices on the Website, in a manner that contained representations regarding the cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to, the diseases listed in Annexure B hereto, and in circumstances where s 42DLB(2) of the TG Act applies because:

- 1.7.1. each representation in respect of each of the diseases is, by r 6B(1)(b) of the TG Regulations and s 30 of the TG Code, a prohibited representation within the meaning of s 42DJ of the TG Act; and
- 1.7.2. no permission under s 42DK of the TG Act was in force in respect of any of the prohibited representations,

in respect of each advertisement, contravened s 42DLB(1) of the TG Act.

- 1.8. the Second Respondent, by causing the First Respondent to advertise HBOT Devices on the Website in the manner and circumstances outlined in paragraph 1.7, contravened s 42DLB(1) of the TG Act.
- 1.9. further, or in the alternative to the declaration sought in paragraph 1.8, the Second Respondent aided, abetted, counselled or procured the First Respondent's contraventions of s 42DLB(1) of the TG Act referred to in the declaration sought in paragraph 1.7 and was therefore involved in those contraventions for the purposes of s 42YC of the TG Act.



2. An order pursuant to s 42YN of the TG Act restraining each of the Respondents for 7 years from the date of this order (whether by themselves, their servants or agents or otherwise) from:
 - 2.1. advertising, or causing or permitting the advertising of, any HBOT Devices unless the relevant HBOT Device is first entered in the Register;
 - 2.2. advertising, or causing the advertising of, any HBOT Devices in a manner that contains the conditions listed in Annexure A without an approval under s 42DF or a permission under s 42DK of the TG Act in force in relation to the restricted representations; and
 - 2.3. advertising, or causing the advertising of, any HBOT Devices in a manner that contains references to the conditions listed in Annexure B without permission under s 42DK of the TG Act in force in relation to the prohibited representations.
3. Orders pursuant to s 42Y of the TG Act that each of the respondents pay to the Commonwealth of Australia such pecuniary penalty as the Court determines appropriate in respect of the contraventions of s 42DLB(1) of the TG Act referred to in paragraph 1 above.
4. An order that the Respondents pay the Applicant's costs of and incidental to these proceedings; and
5. Such further order or orders as the Court sees fit.

CLAIM FOR INTERLOCUTORY RELIEF

The Applicant also claims interlocutory relief:

6. An order under s 42YO of the TG Act that the Respondents be restrained, until further order, whether by themselves or their servants or agents or otherwise howsoever, from promoting or advertising any HBOT Devices unless:
 - 6.1. the HBOT Devices are entered in the Register; and
 - 6.2. the Respondents have given the Secretary of the Department of Health at least 14 days' written notice of their intention to promote or advertise the HBOT Devices.
7. An order under s 42YO of the TG Act that the Respondents be restrained, until further order, whether by themselves or their servants or agents or otherwise howsoever, from promoting or advertising any HBOT Devices in a manner that refers to any of the conditions in Annexure A or B unless:
 - 7.1. an applicable approval under s 42DF or a permission under s 42DK of the TG Act is in force; and
 - 7.2. the Respondents have given the Secretary of the Department of Health at least 14 days' written notice of their intention to promote or advertise the HBOT Devices in a manner that refers to the any of the conditions in Annexure A or B.



8. An order under s 42YO of the TG Act that, within 24 hours of the date of the order and until further order, the Respondents must remove all content from the Website (subject to order 10) until such a time that all statements referring to HBOT Devices are removed from the Website.
9. An order under s 42YO of the TG Act that, within 24 hours of the date of the order and until further order, the Respondents must remove all content from the Website (subject to order 10) until such a time at all statements referring to the conditions listed in Annexure A and B are removed from the Website.
10. An order under s 42YO of the TG Act that:
 - 10.1. the First Respondent, at its expense, within 7 days of this order, cause a notice substantially in the form of Annexure C to this Originating Application to be published and to remain continuously in place, until further order, on the home page of the website at www.oxymed.com.au; and
 - 10.2. the First Respondent shall take all reasonable steps to ensure that such notice shall:
 - 10.2.1. be in a size that consists of at least 50% of the screen area;
 - 10.2.2. be clearly viewable immediately on screen after the web page is accessed;
 - 10.2.3. not be blocked by a pop up blocker;
 - 10.2.4. remain on screen until closed by the person accessing the Website; and
 - 10.2.5. not require the person accessing the website to register on the website or require a further selection of hyperlinks or scrolling on the screen to be seen.
11. An order that the Respondents pay the Applicant's costs of and incidental to the claim for interlocutory relief.

APPLICANT'S ADDRESS

The Applicant's address for service is:

Australia Government Solicitor

Level 24, 600 Bourke Street, Melbourne VIC 3000

Email: glenn.owbridge@ags.gov.au

The Australian Government Solicitor's telephone, facsimile, and document exchange numbers are:

Tel: 03 9242 1222

Fax: 03 9242 1333

DX 50 Melbourne



The Applicant's address is:

PO Box 100

Woden ACT 2606

SERVICE ON THE RESPONDENTS

It is intended to serve this application on all Respondents.

Date: 21 August 2020

A handwritten signature in black ink, appearing to read "Glenn Owbridge", written over a dotted line.

Glenn Owbridge

AGS lawyer

for and on behalf of the Australian Government Solicitor
Lawyer for the Applicant



Annexure A

1. Alzheimer's disease
2. Amyotrophic Lateral Sclerosis
3. Autism Spectrum Disorders
4. Autoimmune Illness
5. Back Pain
6. BioToxins - Cytokine Storm Syndrome
7. Brain Injury
8. Burns
9. Carbon monoxide (CO) poisoning
10. Cellulitis
11. Cerebral Malaria
12. Cerebral Palsy
13. Development Delay
14. Near Drowning (submersion injuries)
15. Hypoxic Induced Encephalopathy
16. Chronic Fatigue Illness
17. Chronic Infections
18. Complex Pain Syndrome
19. Concussion Disability
20. Coronavirus
21. Crohn's Disease
22. Crush Injury
23. Cytokine Storm Syndrome
24. Dementia | Cognitive Decline
25. Disc Prolapse



26. Failed Back Surgery
27. Fibromyalgia
28. Fracture Repair
29. Gadolinium Poisoning
30. Hearing Loss
31. Hospital Infections (MRSA, VRE)
32. Irritable Bowel Syndrome
33. Infertility
34. Kidney Disease
35. Liver Disease
36. Lyme Disease
37. Macular Degeneration
38. Multiple Sclerosis
39. Muscular Dystrophy
40. Motor Neuron Disease
41. Osteoporosis
42. Pancreatitis
43. Paraplegia, Quadriplegia
44. Psoriasis
45. Radiation Necrosis
46. Reflex Sympathetic Dystrophy
47. Spinal Cord Injury
48. Spinal Instability
49. Sensorineural Hearing Loss
50. Stroke
51. Tarlov Cyst



52. Traumatic Brain Injury

53. Ulcerative Colitis



Annexure B

1. AIDS/HIV
2. Cancer
3. Depression
4. Glioblastoma
5. Mental Health
6. Post Traumatic Stress Disorder



Annexure C

The Secretary of the Department of Health has instituted proceedings in the Federal Court of Australia against Oxymed Australia Pty Ltd and Mr Malcolm Hooper alleging breaches of the Therapeutic Goods Act 1989 (Cth).

On [insert date] the Federal Court of Australia issued interim injunctions restraining Oxymed Australia Pty Ltd and Mr Hooper from promoting or advertising Hyperbaric Oxygen Therapy Devices that are not included in the Australian Register of Therapeutic Goods.

Those injunctions can be found at [insert website] and remain in effect until such time as the Court makes further orders.

The Secretary of the Department of Health advises that the Hyperbaric Oxygen Therapy Devices advertised by Oxymed Australia Pty Ltd are not included in the Australian Register of Therapeutic Goods.

The Secretary urges anyone who is suffering from any medical condition, or who wishes to take steps to prevent any such condition, to seek advice from a suitably qualified medical practitioner.