

NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 1/03/2019 5:42:39 PM AEDT 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:	NSD2213/2018
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH v PEPTIDE CLINICS PTY LTD ACN 165 404 286
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised



A handwritten signature in blue ink, reading 'Warwick Soden'.

Dated: 4/03/2019 8:38:35 AM AEDT

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)

AMENDED ORIGINATING APPLICATION

(amended on 1 March 2019 pursuant to Order 2 of the Orders of Jagot J made on 5 February 2019 and Order 1 of the Orders of Jagot J made on 19 February 2019)

**FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: NEW SOUTH WALES
DIVISION: COMMERCIAL AND CORPORATIONS**

NO NSD 2213 OF 2018

SECRETARY OF THE DEPARTMENT OF HEALTH

Applicant

PEPTIDE CLINICS PTY LTD (ACN 165 404 286)

Respondent

To the Respondent,

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 (Sydney)
Law Courts Building
184 Phillip Street
Queens Square, Sydney NSW 2000

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 Department of Health

Prepared by: Sonja Marsic
AGS lawyer within the meaning of s 551 of the *Judiciary Act 1903*

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This is an Application for:

1. declaratory relief under s 21 of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**);
2. an order for a pecuniary penalty for contraventions of a civil penalty provisions under s 42Y of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**);
3. orders for injunctive relief under s 42YN of the TG Act;
4. orders for interim injunctive relief under s 42YO TG Act;
5. costs under s 43 of the FCA Act; and
6. such further or other orders as the Court deems fit,

in respect of conduct by the Respondent, Peptide Clinics Pty Ltd, in connection with the advertising of therapeutic goods (within the meaning of s 3 of the TG Act) as defined and set out in the schedule to the Concise Statement dated 28 November 2018 (**Advertised Products**), that is alleged to contravene ss 42DLB and 42DMA of the TG Act.

The legislative basis of the Court's jurisdiction to hear the present case and to grant the relief sought is found at ss 42Y, 42YN and 42YO of the TG Act and section 21 of the FCA Act.

DETAILS OF CLAIM

On the grounds stated in the Amended Concise Statement dated 1 March 2019 ~~28 November 2018~~, the Applicant seeks:

Declarations

Advertisement of Schedule 4 substances

1. ~~From On and from 6 March 2018 to around 23 November 2018~~, the Respondent contravened s 42DLB(1) of the TG Act by advertising, within the meaning of s 3(1) of the TG Act (**advertising**), therapeutic goods on the publicly accessible part of its website (**Website**) located at Uniform Resource Locator (**URL**) www.peptideclinics.com.au and other webpages publicly accessible from the Website (**Front End of the Website**), such advertisements containing references to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard with the result that s 42DLB(7) of the TG Act applies.
2. ~~On and from From 6 March 2018 to around 7 November 2018~~, the Respondent contravened s 42DLB(1) of the TG Act by advertising therapeutic goods on its Facebook page located at URL <https://www.facebook.com/peptideclinics>, such advertisements containing references to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard with the result that s 42DLB(7) of the TG Act applies.



3. On and from ~~From~~ 6 March 2018 to around 7 November 2018, the Respondent contravened s 42DLB(1) of TG Act by advertising therapeutic goods on its Instagram page located at URL <https://www.instagram.com/peptideclinics>, such advertisements containing references to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard with the result that s 42DLB(7) of the TG Act applies.
4. On and f~~rom~~ 6 March 2018 to 21 December 2018, the Respondent contravened s 42DLB(1) of the TG Act by advertising therapeutic goods on a restricted section of its Website which was only available to consumers who had submitted an online “medical questionnaire” to the Website, which was reviewed by a medical practitioner, and who was then granted access to the restricted section (**Back End of the Website**), such advertisements containing references to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard with the result that s 42DLB(7) of the TG Act applies.

4A. On and from 22 December 2018, the Respondent contravened s 42DLB(1) of the TG Act by advertising therapeutic goods and offering them for sale to consumers over the telephone as part of a process where:

4A.1 a consumer engages in a telephone consultation with a medical practitioner or a person purporting to be a medical practitioner and is recommended certain Schedule 4 substances for use by the consumer depending on the consumer’s goals; and

4A.2 a consumer is then telephoned by a servant, employee or agent of the Respondent where the price of the recommended Schedule 4 substances is explained and the consumer is able to purchase them,

such advertisements containing references to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard with the result that s 42DLB(7) of the TG Act applies.

Restricted representations

5. From 6 March 2018 to around 23 November 2018, the Respondent contravened s 42DLB(1) of the TG Act by advertising therapeutic goods, such advertisements containing representations that referred to serious forms of cardiovascular disease and diseases of joint, bone, collagen, and rheumatic disease, being diseases, conditions, ailments or defects specified in Part 2 of Appendix 6 of the *Therapeutic Goods*



Advertising Code 2015 (Cth) (**2015 Advertising Code**), which were therefore restricted representations in relation to which neither an approval under s 42DF nor a permission under s 42DK was in force such that s 42DLB(4) applies.

Prohibited representations

6. On and from 6 March 2018 to 21 December 2018, the Respondent contravened s 42DLB(1) of the TG Act by advertising therapeutic goods, such advertisements containing representations that referred to anxiety and depression, which are mental illnesses, being a condition specified in Part 1 of Appendix 6 of the 2015 Advertising Code, and which were therefore prohibited representations in relation to which no permission under s 42DK was in force such that s 42DLB(2) applies.

Non-compliance with the Advertising Codes

7. From 6 March 2018 to 23 November 2018, the Respondent contravened s 42DMA(1) of the TG Act by advertising therapeutic goods, such advertisements being non-compliant with s 4(2)(c) of the 2015 Advertising Code in that the advertisements misled, or were likely to have misled, directly or by implication or through emphasis, comparisons, contrasts or omissions.
8. On and from 6 March 2018, the Respondent contravened s 42DMA(1) of the TG Act by advertising therapeutic goods, such advertisements being non-compliant with s 4(2)(i) of the 2015 Advertising Code and s 10(d)(i) of the Therapeutic Goods Advertising Code (No 2) 2018 (Cth) (**2018 Advertising Code**) in that the advertisements contained claims, statements and implications that the advertised products are safe or alternatively, cannot cause harm, when in fact they are not safe and can cause harm.
9. On and from 6 March 2018, the Respondent contravened s 42DMA(1) of the TG Act by advertising therapeutic goods, such advertisements being non-compliant with s 4(2)(f) of the 2015 Advertising Code and s 10(c) of the 2018 Advertising Code in that the advertisements expressly or impliedly encouraged the use of the Advertised Products substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard for the following uses, when such uses would be inappropriate:
 - 9.1. Anxiety/Confidence/Mood Regulation
 - 9.2. Anti-ageing
 - 9.3. Body Building/ Building lean muscle mass/Muscle Building



- 9.4. Tanning/skin pigmentation
- 9.5. Injury repair
- 9.6. Heart Health
- 9.7. Fat/Weight loss
- 9.8. Libido Enhancement
- 9.9. Premature Ejaculation
- 9.10. Female Sexual Dysfunction
- 9.11. Hair Loss
- 9.12. Insomnia Relief/Jet Lag/Sleep assistance

together, the **Advertised Uses**.

- 10. From 6 March 2018 to 23 November 2018, the Respondent contravened s 42DMA(1) of the TG Act by advertising therapeutic goods, such advertisements being non-compliant with s 4(4) of the 2015 Advertising Code in that the advertisements presented scientific information in an inaccurate, imbalanced and misleading manner.

Section 42AA(4) of the Act

- 11. The advertisements the subject of these declarations were not advice or information given directly to a patient by a medical practitioner in the course of treatment of that patient such that the exemption to Part 5-1 of the TG Act set out in s 42AA(4) did not apply.

Injunction

- 12. An order pursuant to s 42YN of the TG Act restraining the Respondent, for a period of five years from the date of this order, whether by itself, its servants or agents from advertising or causing to advertise therapeutic goods if such advertisements:
 - 12.1. refer to substances, or goods containing substances, included in Schedule 4 of the Poisons Standard as in force at the relevant time;



- 12.2. contain restricted representations within the meaning of s 42DD of the TG Act in circumstances in which neither an approval under s 42DF nor a permission under s 42DK is in force in relation to the restricted representations;
 - 12.3. contain prohibited representations within the meaning of 42DJ(1) of the TG Act in circumstances in which no permission under s 42DK is in force in relation to the prohibited representations;
 - 12.4. contain claims, statements and implications that the relevant substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard ~~Advertised Products~~ are safe or alternatively, cannot cause harm, when in fact they are not safe and can cause harm;
 - 12.5. presents scientific information in an inaccurate, imbalanced and misleading manner; and
 - 12.6. expressly or impliedly encourage the use of the relevant substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard ~~Advertised Products~~ for any of the Advertised Uses,
- unless ss 42AA, 42AB or 42AC of the TG Act applies.

Pecuniary penalties

13. An order pursuant to s 42Y of the TG Act that the Respondent pay to the Commonwealth of Australia such pecuniary penalty as the Court determines appropriate in respect of the contraventions of s 42DLB(1) and 42DMA(1) of the TG Act referred in paragraphs 1 to 11 above.

Other orders

14. An order that the Respondent pay the Applicant's costs of and incidental to these proceedings.
15. Such further or other orders that the Court deems fit.

CLAIM FOR INTERLOCUTORY RELIEF

The Applicant also seeks an order for interim injunctive relief pursuant to s 42YO of the TG Act in the following terms:



16. That, within 48 hours of the date of the order, until final orders are made in respect of this Originating Application, the Respondent must:

16.1. Remove all advertisements that contain references to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard from the Front End, including as amended with effect from 22 December 2018, and its Instagram and Facebook pages and ~~Back End of the Website;~~

16.2. ~~Remove all advertisements that contain references to mental illness from the Front End and Back End of the Website~~ Cease causing or permitting discussions by telephone to be undertaken whereby medical practitioners, persons purporting to be medical practitioners, or servants, agents or employees of the Respondent advertise substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard; and

~~16.3. Remove all advertisements that contain claims, statements or implications that the Advertised Products are safe, cannot cause harm and/or have no side effects from the Front End and Back End of the Website;~~ and

16.4. Remove any advertisements that encourage, or are likely to encourage, inappropriate use being any of the Advertised Uses, of substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard ~~the Advertised Products from the Front End and Back End of the Website.~~

17. Alternatively, that, within 48 hours of the date of the order, the Respondent:

17.1. take down or otherwise disable the Website, its Instagram page and its Facebook page such that no part of it them are is publicly accessible; and

17.2. cease causing or permitting discussions by telephone to be undertaken whereby medical practitioners, persons purporting to be medical practitioners, or servants, agents or employees of the Respondent advertise substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard,

until either:

17.3. Final orders are made; or

17.4. The steps described in paragraphs 16.1, 16.2 to and 16.4 are complied with.

APPLICANT'S ADDRESS

The Applicant's address for service is:



Australian Government Solicitor,
Level 42, MLC Centre, 19 Martin Place, Sydney, NSW 2000
Email: Sonja.Marsic@ags.gov.au

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

Tel: 02 9581 7505

Fax: 02 9581 7650

DX 444 Sydney

The Applicant's address is:

PO Box 100
Woden ACT 2606

SERVICE ON THE RESPONDENT

It is intended to serve this application on the Respondent.

Date: ~~28 November 2018~~ 1 March 2019


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Sonja Marsic
AGS lawyer
for and on behalf of the Australian Government Solicitor
Lawyer for the Applicant