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Details of Filing

Document Lodged:	Concise Statement
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

Dated: 29/11/2018 10:47:42 AM AEDT Registrar

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CONCISE STATEMENT

FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: NEW SOUTH WALES
DIVISION: COMMERCIAL AND CORPORATIONS **NO NSD OF 2018**

SECRETARY OF THE DEPARTMENT OF HEALTH
Applicant

PEPTIDE CLINICS PTY LTD (ACN 165 404 286)
Respondent

A. IMPORTANT FACTS GIVING RISE TO THE CLAIM

The Respondent and the Peptide Clinics Website

1. Since at least 2015, Peptide Clinics Pty Ltd (**Respondent**) has operated an online retail business through its website located at Universal Resource Locator (**URL**) www.peptideclinics.com.au (**Website**). Through the Website, the Respondent sells products that are "therapeutic goods" within the meaning provided by s 3(1) of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**). The Respondent describes the therapeutic goods it sells as '**Peptides**' or '**Peptide Treatments**'.

2. The Website also contains information published by the Respondent that asserts a number of purported benefits of Peptides and Peptide Treatments sold by the Respondent including anti-ageing, body building, body fat and weight loss, injury repair, tanning, heart health, mood regulation (including reducing anxiety and depression), libido/sexual function enhancement, preventing sleeplessness, bone health and optimising health and fitness goals.

3. The Respondent also advertises Peptides and Peptide Treatments through its Instagram account (at URL https://www.instagram.com/peptideclinics) and Facebook page (at URL https://www.facebook.com/peptideclinics) (together, **Social Media Channels**).

4. At all relevant times, the Website has described a five step process for purchasing Peptides and Peptide Treatments from the Respondent:

    Step 1: Qualify for Peptide Treatment
    Step 2: Access Online Clinic
    Step 3: Doctor Evaluation
    Step 4: Nurse Consultation
    Step 5: Medication dispatched

5. Pursuant to Step 1, a consumer completes and submits to the Respondent via the Website an online "medical questionnaire". Immediately upon submitting the questionnaire the consumer receives an email requesting the confirmation of his or her email address, which enables the consumer to log in to the Website. Upon providing such confirmation by clicking the link in the email and logging in to their account, the

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consumer is advised via the Website that a "medical professional" will review their medical questionnaire within 24 hours.

6. A short period of time later, the consumer receives an email indicating that they may access a part of the Website not available to the public at large (**Back End**). At the Back End, the consumer has access to additional information about and can purchase Peptides and Peptide Treatments, including the Advertised Products defined at paragraph 8 below. This is Step 2 of the five step process described in paragraph 4 above.

7. Following correspondence between the Applicant and the Respondent, in November 2018, the Respondent made a number of changes to the Website and its Social Media Channels. However, the Respondent continues to advertise therapeutic goods at the Back End of the Website.

Advertisement of Schedule 4 Substances

8. From 6 March 2018 to around 23 November 2018, the Respondent advertised, within the meaning of s 3(1) of the TG Act (**advertised**), the therapeutic goods sold by the Respondent and identified in Schedule 1 to this Concise Statement (**Advertised Products**) on the publicly accessible part of the Website (**Front End**). These advertisements could be accessed by any consumer who searched for products in the search bar on the "login" webpage, moved their cursor over the tabs "PEPTIDES", "COMPOUNDING" and "EDUCATION" on the "login" webpage of the Website or accessed various webpages in the Peptide Treatments and Blog sections of the Website.

9. From 6 March 2018 to around 7 November 2018, the Respondent advertised the Advertised Products on its Social Media Channels.

10. On and from 6 March 2018, the Respondent advertised the Advertised Products at the Back End of the Website. These advertisements are visible to consumers who are given access to the Back End and who viewed webpages accessible from the 'TREATMENTS' and 'EDUCATION' drop down menus.

11. Each of the Advertised Products is listed in Schedule 4 of the current Poisons Standard as indicated in Schedule 1 to this Concise Statement. A number of the Advertised Products are also listed in Appendix D to the current Poisons Standard as indicated in Schedule 1 to this Concise Statement. In New South Wales, it is an offence to possess, or attempt to obtain possession of, the substances listed in Appendix D, being 'prescribed restricted substances' for the purpose of s 16 of the *Poisons and Therapeutic Goods Act 1966* (NSW) without authority. Equivalent legislative provisions exist in all other State and Territories.

Advertisements containing restricted representations

12. On and from 6 March 2018 until around 23 November 2018, the following webpages were accessible from the Website:

    12.1. the webpage at URL www.peptideclinics.com.au/heart-muscle-damage/, which advertises therapeutic good variously described as "TB-500" or "Thymosin Beta-4" and contains representations that expressly or impliedly refer to a serious form of cardiovascular disease.

12.2. the webpage at URL www.peptideclinics.com.au/how-to-increase-bone-density/, which advertises a therapeutic good described as "SARMS Forte" and contains representations that expressly or impliedly refer to a serious form of joint, bone, collagen, and rheumatic disease.

12.3. the webpage at URL www.peptideclinics.com.au/treatments/osteopenia/, which advertises therapeutic goods and contains representations that expressly refer to osteopenia, a disease of the bone.

13. The diseases, or alternatively, conditions and ailments, referred to in the preceding paragraph were each serious forms of those diseases, conditions or ailments within the meaning of s 5(2) of the *Therapeutic Goods Advertising Code 2015* (**Advertising Code**) and Part 2 of Appendix 6 of the Advertising Code since they are generally accepted:

13.1. not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or

13.2. to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

14. Consequently, the representations referred to in paragraph 12 above were restricted representations within the meaning of s 42DD of the TG Act.

15. At no time has the Secretary of the Department of Health granted approval to the Respondent under s 42DF(1) of the TG Act or a permission under s 42DK(1) of the TG Act to use the restricted representations.

Advertisements containing prohibited representations

16. On and from 6 March 2018, the Respondent has advertised the use of "5HTP" (5-Hydroxytryptophan) and Oxytocin, being therapeutic goods, for treatment of 'anxiety', as well as more general references to the use of Peptides for anxiety, depression and 'mood regulation' (for example, the webpage at URL www.peptideclinics.com.au/treatments). These advertisements contain representations that expressly and impliedly referred to the treatment, cure or prevention of mental illness.

17. The representations referred to in the preceding paragraph are referred to in s 5(1) and Part 1 of Appendix 6 of the Advertising Code and are therefore prohibited representations within the meaning of s 42DJ(1) of the TG Act.

18. At no time has the Secretary of the Department of Health granted permission under s 42DK of the TG Act to use the prohibited representations.

Non-compliance with the Advertising Code

19. From 6 March 2018 to around 23 November 2018, the Respondent advertised therapeutic goods on its Website in a way that would mislead, or be likely to mislead, consumers directly or by implication or through emphasis, comparisons, contrasts or omissions, and which thereby did not comply with s 4(2)(c) of the Advertising Code.

20. From 6 March 2018 to around 23 November 2018, the Respondent advertised the Advertised Products on its Website in a way that encouraged the use of the Advertised Products for uses including:

    20.1. anti-ageing, bodybuilding, fat loss, injury repair, tanning, heart health, mood regulation and sleep loss (From 6 March 2018 to around 23 November 2018, on the webpage at URL www.peptideclinics.com.au/treatments); and

    20.2. anxiety, anti-ageing, bodybuilding, fat loss, female sexual dysfunction, hair loss, injury repair, libido enhancement, muscle building, premature ejaculation, skin pigmentation/tanning and/or sleep assistance (on and from 6 March 2018, under the 'TREATMENTS' tab visible when logged in to the Back End of the Website)

    when such uses would be inappropriate, and which thereby did not comply with s 4(2)(f) of the Advertising Code.

21. From 6 March 2018 to around 23 November 2018, on the webpage at URL www.peptideclinics.com.au/treatments/sun-safety-australia/, the Respondent advertised therapeutic goods in a way that implied that the use of Melanotan II for the purpose of self-tanning is safe or alternatively, cannot cause harm, when in fact it is not safe and can cause harm, and which thereby did not comply with s 4(2)(i) of the Advertising Code;

22. On and from 6 March 2018, the Respondent advertised on the Website, including at the following webpages, the Advertised Products in a way that implied that the Advertised Products were safe or alternatively, cannot cause harm, when in fact they are not safe and can cause harm, and which thereby did not comply with s 4(2)(i) of the Advertising Code.

    22.1. https://www.peptideclinics.com.au/store/vip/medical/index/.

    22.2. www.peptideclinics.com.au, under the tabs 'Why Choose us?' and 'Online Medical Evaluation, Approval and Despatch [sic]'; and

    22.3. https://www.peptideclinics.com.au/peptides-australia/

    22.4. the webpages accessible under the 'TREATMENTS' and 'EDUCATION' tabs at the Back End of the Website.

23. From 6 Mach 2018 to around 23 November 2018, the webpage referred to at paragraph 21 referred to a clinical study purportedly finding that "only 5% of the sunscreens that were tested held up to safety standards" and "another 40% were said to contribute to developing skin cancer" thus referring to scientific information, which was not presented in a manner that was accurate, balanced and not misleading, and which thereby did not comply with s 4(4) of the Advertising Code.

Application of Part 5-1 of the TG Act to Back End advertisements

24. To the extent that a medical practitioner is responsible for "approving" the consumer's access to the Back End of the Website, he or she is not in a doctor/patient relationship with that consumer, because:

24.1. There has been no engagement between the medical practitioner and the consumer, including by the medical practitioner to discuss the responses to the medical questionnaire with the consumer;

24.2. The information gathered in the medical questionnaire is not sufficient for the medical practitioner to take a medical history, determine whether any further examination is required or to recommend a course of treatment;

24.3. The medical practitioner has not evaluated or diagnosed a condition, nor are they able to on the basis of the medical questionnaire;

24.4. The medical practitioner has a conflict of interest that means they are not acting in the consumer's best interests.

25. In "approving" the consumer accessing the Back End of the Website and thereby advertising the Advertised Products to the consumer, the requirements of s 42AA(4) of the Act were not satisfied since:

25.1. for the reasons set out in paragraph 24 above, the consumer was not a "patient" of any medical practitioner engaged by the Respondent at the time the consumer was "approved" to access the Back End of the Website; and

25.2. further or alternatively, advice or information was not provided directly by a medical practitioner or nurse engaged by the Respondent to a patient in the course of granting the consumer access to the Back End of the Website; and

25.3. further or alternatively, at no time before the consumer was granted access to the Back End of the Website was he or she in a course of treatment with a medical practitioner engaged by the Respondent.

B. THE RELIEF SOUGHT FROM THE COURT

26. The Applicant seeks the relief set out in the accompanying Originating Application, comprising:

26.1. declarations pursuant to s 21 of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**);

26.2. orders for injunctive relief under s 42YN of the TG Act;

26.3. orders for interim injunctive relief under s 42YO TG Act;

26.4. pecuniary penalties pursuant to s 42Y of the TG Act; and

26.5. costs under s 43 of the FCA Act.

C. THE PRIMARY LEGAL GROUNDS FOR THE RELIEF SOUGHT

27. By reason of the conduct described in paragraphs 1 and 8 to 11, which involves advertisements referring to substances or goods containing substances included in Schedule 4 to the current Poisons Standard, the Respondent contravened s 42DLB(1) of the TGA since s 42DLB(7) applies.

28. By reason of the conduct described in paragraphs 1 and 12 to 15, which involves advertisements containing restricted representations, the Respondent contravened s 42DLB(1) of the TGA since s 42DLB(4) applies.

29. By reason of the conduct described in paragraphs 1 and 16 to 18, which involves advertisements containing prohibited representations, the Respondent contravened s 42DLB(1) of the TGA since s 42DLB(2) applies.

30. By reason of the conduct described in paragraphs 1 and 18 to 21, which involves advertisements that do not comply with the Advertising Code, the Respondent contravened s 42DMA(1) of the TG Act.

D. THE ALLEGED HARM SUFFERED

31. The harm suffered by consumers by reason of the contraventions outlined above includes serious harm and risk of serious harm to their health and safety. The use, particularly the use without appropriate medical supervision, of the Advertised Products carries substantial risks to human health.

32. The public generally is exposed to harm and/or risk of harm by the publication of misleading information that suggests that the Advertised Products are safe and appropriate for the advertised uses (when they are not).

33. The public generally is also exposed to harm and/or risk of harm by the publication of misleading information about important public health issues such as healthy body image and the use of sunscreen in the prevention of skin cancer.

34. The harm caused is of particular concern as the Respondent's conduct misleads the public into thinking that the consumer's use of the products is being supervised or approved by a medical practitioner (when it is not).

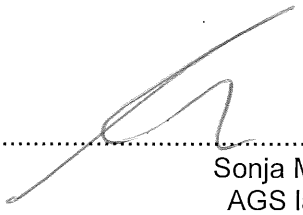
35. The harm suffered also includes financial loss in purchasing the Advertised Products from the Respondent.

36. By supplying those Advertised Products that are listed in Appendix D of the current Poisons Standard to consumers without providing the consumers with a prescription, nor informing consumers that the products cannot be lawfully possessed without a prescription, the Respondent exposes consumers to the risk of prosecution.

CERTIFICATE OF LAWYER

I, Sonja Marsic, certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 28 November 2018



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

SCHEDULE 1 TO CONCISE STATEMENT

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
1.	AOD 9604	N/A	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
2.	Bremelanotide (PT-141)	March 2018: afamelanotide (cross-referenced to melanocyte stimulating hormone) June and October 2018: Alpha-melanocyte stimulating hormone, or melanotan II	Yes (as afamelanotide)	No	Yes	No	Yes	Yes – to Melanotan II	No	Yes
3.	CJC-1295	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
4.	Finasteride	N/A	Yes	No	Yes	No	Yes	No	No	Yes
5.	Follistatin 315-R	Follistatins	Yes	Yes	Yes	Yes	Yes	No	No	Yes
6.	Growth Hormone Releasing Peptide (GHRP)-2	Growth Hormone Releasing Peptides	Yes	Yes	Yes	Yes	Yes	No	No	Yes

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
7.	Growth Hormone Releasing Peptide-6 (GHRP-6)	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
8.	GH combinations comprised of the following: CJC-1295 + Ipamorelin CJC-1295 + GHRP-6	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
9.	HBS Prescription Serum, comprised of: Minoxidil(10%) Dutasteride Latanoprost Melatonin	N/A	Yes	No	Yes	No	Yes	No	No	Yes
10.	IGF-1 (Insulin Like Growth Factor-1) LR3	Insulin Like Growth Factor-I Insulin Like Growth Factors except when separately specified in this Schedule	Yes	Yes	Yes	Yes	Yes	No	No	Yes

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
11.	Ipamorelin	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
12.	Mechano growth factor	Insulin Like Growth Factor-I Insulin Like Growth Factors except when separately specified in this Schedule	Yes	Yes	Yes	Yes	Yes	No	No	Yes
13.	Melanotan II	Until 1 June 2018: afamelanotide (cross-referenced to melanocyte stimulating hormone)	Yes (as afamelanotide) – introduced into Schedule 4 in the Poisons Standard June 2018 as melanotan II with effect from 1 June 2018.	No	Yes	No	Yes	Yes	Yes	Yes
14.	Melatonin	N/A	Yes	No	Yes	No	Yes	Yes	Yes	Yes
15.	Minoxidil	Minoxidil except when included in Schedule 2 Schedule 2: Minoxidil in preparations for dermal use containing 5% or less of minoxidil	Yes	No	Yes	No	Yes	No	No	Yes

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
16.	Oxytocin	N/A	Yes	No	Yes	No	Yes	No	No	Yes
17.	Selectic Androgen Receptor Modulators (SARMs) s22 (Forte)	Selective Androgen Receptor Modulators	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18.	Thymosin Beta 4	N/A	Yes	No	Yes	No	Yes	No	Yes	Yes