



11 May 2023

Gynecological disorder patents granted by US Patent and Trademark Office

HIGHLIGHTS

- Ecofibre has received patent grant notifications for two of the five patent applications it filed in October 2022 with the US Patent and Trademark Office (USPTO), and has paid issue fees and awaiting formal grant notification on a third patent application.
- Patents granted include the treatment for Ovarian Cancer, the treatment of Endometriosis. The formal patent grant date of these patents is 23 May 2023.
- The Endometriosis patent includes the therapeutic application of cannabinoids for Fibroids and Dysmenorrhea (period pain)
- The third patent upon which issue fees have been paid is Ecofibre's proprietary System and Method for Producing Hemp Extracts.
- Two remaining patent applications filed in October 2022 for the treatment of Head and Neck Cancer and Endometrial Cancer are under review with the USPTO
- Post granting of patents, Ecofibre is focused on partnerships to commercialise treatment and management options for gynecological diseases

Ecofibre Limited (Ecofibre, Company) (ASX: EOF) announces that the United States Patent and Trademark Office has sent issue notifications for two patents in relation to the Company's ongoing research program with the University of Newcastle (Newcastle).

In October 2021, the Company filed five provisional patent applications ([see ASX announcement](#)), and subsequently, in October 2022, the final utility applications were submitted to the USPTO. The patent grant process is as follows: allowance notifications are sent, issue fees are paid, issue notifications are sent (with patent number, issue date and any patent term extensions noted) and the patent is issued.

The supporting data for the gynaecological patent applications was derived from Ecofibre's ongoing gynecological disorder research study with the University of Newcastle's [Global Centre for Gynaecological Diseases](#). The patents have been granted jointly to both parties.






The issue fees have been paid for Ecofibre's proprietary System and Method for Producing Hemp Extracts and the remaining two remaining patent applications for the treatment of Head and Neck Cancer and Endometrial Cancer are under review with the USPTO.

The following table provides an overview of the status of our patent filings.

Patents Overview

Five patent applications involving the use of cannabinoids in treating patients in the following areas

 <p>Gynecological cancer Accounts for over 15% of cancers diagnosed in women globally, some with five-year survival rates ranging 17-39%</p>	 <p>Endometriosis Affects 11% of reproductive age women globally, causing severe pain and infertility – often extends post menopause</p>	 <p>Head and neck cancer Accounts for ~4% of all cancer diagnosis, and incidence increasing in recent years among younger people</p>
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US Patent Application No.	USPTO/PCT Application Date	US Patent Number	Patent Status	Name of Patent
18/049,961	26 Oct 2022	11,654,171	Issue date – 5/23/23	Methods of Treating Ovarian Cancer with Hemp Extract
18/049,966	26 Oct 2022		Under Review	Methods of Treating Head and Neck Cancers with Hemp Extract
18/049,977	26 Oct 2022		Issue Fees Paid	Systems and Methods for Producing Hemp Extracts and Compositions
18/050,021	26 Oct 2022		Under Review	Methods of Treating Endometrial Cancer Using Hemp Extract
18/050,023	26 Oct 2022	11,654,172	Issue date – 5/23/23	Methods of Treating Endometriosis and Other Non-Cancer Gynecological Disorders with Hemp Extract

These patents protect key methodology components such as pH range, dosage levels (composition), and delivery (oral, intravaginal, etc.)

Ecofibre CEO Eric Wang said, "I am very pleased that the USPTO has approved these important patents and that the approvals have been obtained so quickly."

"Today's news allows us to move to the next stage of our research program in several key areas for women's health and to continue developing new treatment and management options for gynecological disorders. In combination with these clinical research findings, the manufacturing patent is also an important step toward the commercialization of our intellectual property. Ecofibre is now engaging with potential financial partners with commercialisation options."

The Company will continue to keep the market updated.

Ecofibre's Chief Science Officer and women's health practitioner Dr. Alex Capano said, "The Ovarian Cancer and Endometriosis patents are significant milestones in Ecofibre's clinical research program and are an outcome of our ongoing commitment to women's health over many years."

"Gynaecological cancers account for over 15% of cancers diagnosed in women globally. They are frequently diagnosed in late stages, considerably aggressive, difficult to treat, and often result in metastatic disease. The five-year survival rates for certain gynaecological cancers range from 17-39%. The need for improved therapeutic options is clear."



"The global market size for Endometriosis and Dysmenorrhea was \$6.9B in 2023, with the US representing just under 50% of this market. These conditions have very few quality treatment options today."

Professor Pradeep Tanwar, the Director of the University of Newcastle's Global Center for Gynecological Diseases, stated, "The issue notifications for these patents shows the value of our organoid-based research approach. We are well positioned to move to the next stage of our research, which includes full protocol development for eventual human trials."

Background - Patents

Methods of Treating Ovarian Cancer with Hemp Extract

- *US Patent Number:* 11,654,171
- *Issue date:* 23 May 2023
- *Owner/s:* Ecofibre Limited and The University of Newcastle
- *Term:* 20 years from the filing date
- *Subject matter claimed:* The claims are generally directed towards methods of treating ovarian cancer by intravaginal administration of a composition comprising a cannabis extract, the cannabis extract having between 50 and 99% of cannabidiol (CBD) and a pH of between 3.5 and 6, which is administered in conjunction with one or more of sixteen (16) enumerated chemotherapeutic agents.

Methods of Treating Endometriosis and Other Non-Cancer Gynecological Disorders with Hemp Extract

- *US Patent Number:* 11,654,172
- *Issue date:* 23 May 2023
- *Owner/s:* Ecofibre Limited and The University of Newcastle
- *Term:* 20 years from the filing date
- *Subject matter claimed:* A method for treating a non-cancerous gynecological disorder selected from ovarian endometrioma, deep endometriosis, dysmenorrhea, and fibroids by administering to a patient a composition comprising a cannabis extract containing cannabidiol (CBD) and having a pH of between 3.5 and 6.



Systems and Methods for Producing Hemp Extracts and Compositions

- *US Patent Number:* TBD
- *Issue date:* TBD
- *Owner:* Ecofibre Limited
- *Term:* 20 years from the filing date
- *Subject matter claimed:* A method for creating a full spectrum hemp extract from cannabis sativa, comprising: extraction via a solvent of heptane and ethanol; distilling off a portion of the solvent and collecting a concentrate; further refining the concentrate by performing a partition and collecting the nonpolar solvent; evaporating the partition to remove the remaining solvent to create a crude oil; degassing the crude oil; and finally, performing a first and second pass distillation to collect the full spectrum hemp extract. Each of the above steps includes additional temperature limitations required to obtain the desired products selectively.

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About Ecofibre

Ecofibre is a diversified industrial hemp company in the United States and Australia.

We operate three vertically integrated businesses focused on growth in natural health care, plant-based foods, and sustainable product solutions.

Ananda Food owns one of the world's largest collections of hemp seed genetics. It is a leading, low-cost manufacturer of highquality hemp food products in Australia, including oil, seed, and proteins. See anandafood.com.

Ananda Health is a leading US manufacturer of hemp-based nutraceuticals for the professional market. We produce CBD products for human and pet consumption and topical health and beauty products. Our focus on high-quality, efficacious, and safe products is supported by a commitment to clinical research in Australia and the USA, focused on conditions including sleep, pain, anxiety, endometriosis, and gynecological diseases. See anandaprofessional.com. Ananda Hemp provides Australians with medicinal cannabis products as part of the SAS-B program. Ananda Hemp offers a range of products manufactured at our US facility under the S4 and S8 categories. See anandahemp.com.au.

Hemp Black is an industrial business focused on textiles and bioplastics, with specialist capabilities in yarn extrusion, knitting, and polymer compounding. We use innovative hemp-based composite technology to help de-carbonise consumer products and supply chains for various industries. See hempblack.com.

Authorisation

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