T-2108-23

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Court File No. T-2108-23

FEDERAL COURT
COUR FÉDÉRALE
FILED
OCT 06 2023
BRITTNEY CHANNER
TORONTO, ON
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FEDERAL COURT

B E T W E E N:

BOEHRINGER INGELHEIM (CANADA) LTD.

Applicant

- and -

**THE MINISTER OF HEALTH,
ATTORNEY GENERAL OF CANADA and
JAMP PHARMA CORPORATION**

Respondents

NOTICE OF APPLICATION

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the applicant. The relief claimed by the applicant appears below.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the applicant. The applicant requests that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must file a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the applicant's solicitor or, if the applicant is self-represented, on the applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

YOGINDER GULIA
REGISTRY OFFICER
AGENT DU GREFFE

Date: October 6, 2023 Issued by: _____

Address of local Office:
180 Queen Street
Suite 200
Toronto, Ontario
M5V 3L6

TO: **MINISTER OF HEALTH**
Health Canada
Address Locator 1801B
Ottawa, Ontario
K1A 0K9

(Service effected pursuant to Rules 133(1) and 304(1)(b)(i) of the *Federal Courts Rules*)

AND TO: **ATTORNEY GENERAL OF CANADA**
Ontario Regional Office
Department of Justice Canada
120 Adelaide Street West
Suite #400
Toronto ON
M5H 1T1

(Service effected pursuant to Rules 133(1) and 304(1)(b)(iii) of the *Federal Courts Rules*)

AND TO: **JAMP PHARMA CORPORATION**
1310 Nobel Street
Boucherville, QC
J4V 5H3

APPLICATION

This is an application for judicial review in respect of the September 6, 2023 decision of the Minister of Health (the "Decision") to grant the respondent, JAMP Pharma Corporation ("JAMP"), a notice of compliance ("NOC") for JAMP Nintedanib 150 mg nintedanib (as nintedanib esylate) capsules ("JAMP Nintedanib 150 mg").

THE APPLICANT MAKES APPLICATION FOR:

a. An order quashing the Decision and the NOC issued as a result of the Decision;

b. An order precluding the Minister of Health from issuing a notice of compliance for JAMP Nintedanib 150 mg, without the 100 mg strength of nintedanib (as nintedanib esylate);

c. The costs of this application; and

d. Such further and other relief as this Honourable Court may deem just.

THE GROUNDS FOR THE APPLICATION ARE:

A. The Parties

1. The applicant Boehringer Ingelheim (Canada) Ltd. ("BI Canada") is a company incorporated under the laws of Canada. BI Canada has its registered office at 5180 South Service Road, Burlington, Ontario L0R 2A0. BI Canada is a plaintiff in an ongoing patent infringement action against JAMP in relation to nintedanib (described below).

2. BI Canada markets and distributes innovative pharmaceutical products, including OFEV®.

3. The Minister of Health is responsible for reviewing and approving submissions for drugs in Canada.

4. The respondent JAMP markets generic pharmaceuticals and has an office at 130 Nobel Street, Boucherville, Quebec, Canada.

B. OFEV

5. BI Canada markets and sells nintedanib esilate capsules in Canada in strengths of 100 mg and 150 mg of nintedanib under the brand name OFEV®, pursuant to Notices of Compliance issued by the Minister of Health.

6. The "INDICATIONS" section of the approved OFEV® product monograph provides, in part, that

> OFEV (nintedanib) capsules are indicated for:
>
> - The treatment of Idiopathic Pulmonary Fibrosis (IPF)
> - To slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD)
> - The treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (also known as progressive fibrosing ILD) (see 14 CLINICAL TRIALS)

7. Treatment with OFEV® requires close oversight and monitoring by health care professionals. BI Canada has a risk management plan and a patient support program for OFEV®.

8. OFEV® is the only nintedanib product marketed in Canada.

C. The PMNOC Action

9. On June 17, 2022, BI Canada received a letter from JAMP, which was asserted to be a "Notice of Allegation" pursuant to the *Patented Medicines (Notice of Compliance) Regulations* ("JAMP Letter").

10. The JAMP Letter referred to nintedanib capsules in strengths of 100 mg and 150 mg (the "JAMP Products").

11. The JAMP Letter asserted that JAMP had filed with the Minister of Health an abbreviated new drug submission, No. 262177 ("ANDS"), seeking a Notice of Compliance for the JAMP Products.

12. On July 28, 2023, Boehringer Ingelheim International GmbH ("BII") and BI Canada brought an action pursuant to section 6(1) of the *PMNOC Regulations* seeking a declaration that the selling, *etc.* of the JAMP Products in accordance with the ANDS would infringe or induce infringement of two Canadian patents owned by BII. BII and BI Canada waived the statutory stay pursuant to section 7(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations* at the time the action was commenced.

D. The Decision

13. On September 6, 2023, the Minister of Health issued the NOC for JAMP Nintedanib 150 mg. The NOC did not refer to a 100 mg strength capsule.

14. JAMP Nintedanib 150 mg is a generic version of BI Canada's OFEV® 150 mg strength product.

15. The NOC identifies OFEV® as the Canadian reference product.

E. The JAMP product monograph

16. The JAMP Nintedanib product monograph, approved by the Minister of Health, recommends a dose reduction to 100 mg twice daily in certain circumstances, but repeatedly advises that a 100 mg strength of JAMP Nintedanib is not available.

17. The "Recommended Dose and Dosage Adjustment" section of the approved JAMP product monograph provides, in part, that:

- The recommended dose of JAMP Nintedanib is 150 mg twice daily administered approximately 12 hours apart.
- Dose adjustments due to adverse reactions
    - In addition to symptomatic treatment if applicable, the management of adverse reactions of nintedanib could include dose reduction (to 100 mg* twice daily) and temporary

interruption of nintedanib treatment until the specific adverse reaction has resolved to levels that allow continuation of therapy. JAMP Nintedanib treatment may be resumed at the full recommended dose (150 mg twice daily) or a reduced dose (100 mg* twice daily). If a patient does not tolerate 100 mg* twice daily, treatment with nintedanib should be discontinued (see 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

*JAMP Nintedanib is NOT available in 100 mg strength

- Cases of drug-induced liver injury (DILI), have been reported in patients treated with nintedanib. In the majority of cases, the DILI was reversible when the dose was reduced or treatment was stopped.
  - Treatment interruption or dose reduction to 100 mg* twice daily is recommended for patients whose transaminase (AST or ALT) are measured greater than 3 times to less than 5 times the upper limit of normal (ULN) without signs of liver damage. These patients should be monitored closely. Alternative causes of the liver enzyme elevations should be investigated. Once transaminases have returned to baseline values, treatment with nintedanib may be reintroduced at a reduced dose (100 mg* twice daily) which subsequently may be increased to the full recommended dose (150 mg twice daily) (see 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

*JAMP Nintedanib is NOT available in 100 mg strength.

  - Treatment with JAMP Nintedanib should be permanently discontinued 1) if transaminase (AST or ALT) elevations are greater than 5 times ULN, or 2) if transaminase (AST or ALT) elevations are greater than 3 times ULN with clinical signs or symptoms of liver injury which may include fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice (see 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

- Hepatic impairment
  - Mild hepatic impairment: In patients with mild hepatic impairment (Child Pugh A), the recommended dose of nintedanib is 100 mg* twice daily approximately 12 hours apart. Treatment interruption or discontinuation for management of adverse reactions should be considered

*JAMP Nintedanib is NOT available in 100 mg strength.

18. The "WARNINGS AND PRECAUTIONS" section of the approved JAMP product monograph provides, in part, that:

> Diarrhea should be treated at first signs with adequate hydration and anti-diarrheal medication (e.g., loperamide) and may require dose reduction or treatment interruption. Nintedanib treatment may be resumed at a reduced dose (100 mg* twice daily) or at the full recommended dose (150 mg twice daily). If severe diarrhea persists despite symptomatic treatment, treatment with nintedanib should be discontinued.
> *JAMP Nintedanib is NOT available in 100 mg strength.
>
> Nausea and vomiting
>
> Nausea and vomiting were frequently reported adverse events (see 8 ADVERSE REACTIONS). In most patients with nausea and vomiting, the event was of mild to moderate intensity. In clinical trials, nausea or vomiting infrequently led to discontinuation of treatment with nintedanib.
>
> If symptoms persist despite appropriate supportive care (including anti-emetic therapy), dose reduction or treatment interruption may be required. The treatment may be resumed at a reduced dose (100 mg* twice daily) or at the full recommended dose (150 mg twice daily). If severe nausea or vomiting persists despite symptomatic treatment, discontinue treatment with JAMP Nintedanib.
>
> Diarrhea and vomiting may lead to dehydration with or without electrolyte disturbances which may progress to renal function impairment.
> *JAMP Nintedanib is NOT available in 100 mg strength.

F. Grounds of Review

19. The applicant submits that the Minister of Health erred, including in law, and in the alternative was unreasonable in making the Decision, *inter alia*, as follows:

a. In issuing the NOC for JAMP Nintedanib 150 mg, without the 100 mg strength, when the 100 mg strength is required for dose reduction purposes as referenced in the approved product monograph for JAMP Nintedanib 150 mg;

b. Failing to consider the prejudice to the applicant and its OFEV® product caused by issuing the NOC for only the 150 mg strength for JAMP's nintedanib capsules; and

c. Failing to consider the impact on patient safety caused by issuing the NOC for only the 150 mg strength for JAMP's nintedanib capsules without approval of the lower strength recommended for safety reasons.

20. The applicant relies upon:

a. Sections 18, 18.1 and 18.2 of the *Federal Courts Act*, R.S.C . 1982, c. F-7, as amended;

b. The *Food and Drugs Act;*

c. Division 8 of the *Food and Drug Regulations*, C.R.C., c. 870, as amended;

d. The *Federal Courts Rules*, Rule 300 *et seq.*; and

e. Such further and other grounds as counsel may advise and this Honourable Court may permit.

G. Venue

21. The applicant requests that this application be heard at Toronto, Ontario.

THIS APPLICATION WILL BE SUPPORTED BY the following material:

a. The Decision;

b. The affidavits of one or more individuals to be filed; and

c. Such further material as the applicant may advise and this Honourable Court may permit.

THE APPLICANT REQUESTS THAT the Minister of Health send a certified copy of the following material that is not in the possession of the applicant but is in the possession of the Minister of Health to the applicant and to the Registry:

a. All materials and communications between JAMP and the Minister of Health relating to the Decision;

b. All materials relating to any notification by the Minister of Health to JAMP under section C.08.004(3)(b) of the *Food and Drug Regulations* of non-compliance with the requirements of section C.08.002.1 of the *Food and Drug Regulations*;

c. All materials relating to any cancellation and/or withdrawal of JAMP's 100 mg nintedanib product from the ANDS, including (i) any communications between JAMP and the Minister of Health related to same and (ii) any materials relating to any revisions to the JAMP product monograph resulting from same;

d. Material forming any part of the Minister of Health's analysis to issue the NOC for only the 150 mg strength nintedanib capsule;

e. Evidence in support of the Decision;

f. Materials forming reasons for the Decision; and

g. Such further and other documents in the Minister of Health's possession which pertain to the Decision and/or otherwise relate to a matter raised in this application.

October 6, 2023

FOR: **SMART & BIGGAR LLP**
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Solicitors for the Applicant

Court File No. T- -23

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Solicitors for the Applicant

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the OCT 06 2023 day of _____ A.D. 20___

Dated this ___ day of OCT 06 2023 20___

_____