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		May 22, 2026	É
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Kadara Thompson			
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Court File No. T- -26

FEDERAL COURT

BETWEEN:

SALIX PHARMACEUTICALS INC.

Plaintiff

- and -

APOTEX INC.

Defendant

STATEMENT OF CLAIM

TO THE DEFENDANT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by Plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or a solicitor acting for you are required to prepare a statement of defence in Form 171B prescribed by the *Federal Courts Rules*, serve it on Plaintiff's solicitor or, if Plaintiff does not have a solicitor, serve it on Plaintiff, and file it, with proof of service, at a local office of this Court

WITHIN 30 DAYS after the day on which this statement of claim is served on you, if you are served in Canada or the United States; or

WITHIN 60 DAYS after the day on which this statement of claim is served on you, if you are served outside Canada and the United States.

TEN ADDITIONAL DAYS are provided for the filing and service of the statement of defence if you or a solicitor acting for you serves and files a notice of intention to respond in F01m 204.1 prescribed by the *Federal Courts*

Rules.

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 DEFEND THIS PROCEEDING, judgment may be given against you in your absence and without further notice to you.

Issued by:

Issued on: May 25, 2026

Issued by: Kadara Thompson (Registry Officer)

Address of Local Office: 90 Sparks Street/rue Sparks Ottawa, Ontario K1P 5R5

(Registry Officer)
Federal Court
90 Sparks Street
Ottawa ON K1P 5A5

TO: Apotex Inc.
150 Signet Drive Toronto, Ontario M9L 1T9
Attention: Patrick Hui

CLAIM

1. Plaintiff claims:

- a) a declaration pursuant to section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the “*Regulations*”) and rule 64 of the *Federal Courts Rules*, that the Defendant’s making, constructing, using, selling, offering for sale, importing or exporting of its 550 mg rifaximin tablets (“APO-RIFAXIMIN”) in accordance with the Abbreviated New Drug Submission Control No. 305344 referenced in the Defendant’s letter dated April 9, 2026 (the “Apotex Letter”), would infringe, directly or indirectly, or induce infringement of, at least one of claims 1 to 19 of Canadian Patent No. 2,739,436 (the “436 Patent”);
- b) an injunction pursuant to section 57(1) of the *Patent Act*, R.S.C. 1985, c. P-4, as amended (the “*Patent Act*”) and paragraph 7(1)(e) of the *Regulations*, restraining the Defendant and any person over whom the Defendant exercises control from directly or indirectly making, constructing, using, selling, offering for sale, importing or exporting APO-RIFAXIMIN, or inducing anyone else to do so, until the expiry of the 436 Patent;
- c) an order directing that the Defendant shall forthwith deliver up to Plaintiff, or destroy under oath, all goods in its possession or power used, made, imported or being made that infringe the 436 Patent;
- d) an order according to section 6.12 of the *Regulations* for costs of this action in an amount acceptable to the Court; and
- e) such further and other relief as this Honourable Court deems just.

The Nature of This Action

2. This is an action under section 6 of the *Regulations* in response to the Apotex Letter dated April 9, 2026, which was served upon Plaintiff, Salix Pharmaceuticals,

Inc. (“Salix”), via service upon Bausch Health Companies Inc. (“Bausch Health”) by the Defendant Apotex Inc. (“Apotex”). The Apotex Letter purports to be a Notice of Allegation (“NOA”) pursuant to section 5 of the *Regulations*. The Apotex Letter addresses the 436 Patent.

Apotex Rifaximin Product

3. Apotex has filed an Abbreviated New Drug Submission (“ANDS”), Submission Control No. 305344 (the “Apotex ANDS”) seeking a Notice of Compliance (“NOC”) in respect of APO-RIFAXIMIN. The Apotex ANDS compares APO-RIFAXIMIN to Salix’s rifaximin drug, which is sold under the brand name ZAXINE® in Canada.

4. The Apotex ANDS is seeking approval for Apotex’s 550 mg rifaximin tablets for oral administration. APO-RIFAXIMIN will contain the medicinal ingredient rifaximin. Apotex is seeking approval for APO-RIFAXIMIN, which will be used for the reduction in risk of overt hepatic encephalopathy (“HE”) recurrence in patients 18 years of age and older.

5. Rifaximin is also the active ingredient in ZAXINE®, a drug product that is marketed and sold in Canada by Lupin Pharma Canada Ltd. (“Lupin Canada”), as the exclusive distributor of ZAXINE® in Canada.

The Parties

6. Plaintiff Salix is a corporation existing under the laws of the State of New Jersey, U.S.A., with its principal place of business located at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey, 08807, U.S.A. Salix is a wholly owned subsidiary of Bausch Health and is the owner of the 436 Patent. Salix holds NOCs in respect of ZAXINE® and is a first person as that term is used in subsections 4(1) and 6(1) of the *Regulations*.

7. Defendant Apotex is a corporation existing under the laws of the Province of Ontario, having a principal office or place of business at 150 Signet Drive, Toronto, Ontario, Canada. Apotex manufactures and sells generic pharmaceuticals and biosimilars in Canada.

ZAXINE®

8. ZAXINE® is a first-in-class long-term antibiotic treatment for HE with a broad antimicrobial spectrum against many gram-positive, gram-negative, aerobic and anaerobic bacteria. The active ingredient in ZAXINE®, rifaximin, is a non-aminoglycoside semi-synthetic antibacterial derived from rifamycin SV. Rifaximin acts by binding to RNA polymerase, inhibiting the synthesis of bacterial RNA.

9. Rifaximin reduces the recurrence of overt HE by decreasing the bacterial toxin load on cirrhotic livers. This acts to decrease inflammatory responses to toxins in the central nervous system, which precipitates HE episodes.

10. ZAXINE® is indicated for the reduction in risk of overt HE recurrence in patients over 18 years of age, and the treatment of irritable bowel syndrome with diarrhea in adults.

11. Salix has permission to market ZAXINE® in Canada pursuant to NOCs dated August 13, 2013, December 3, 2018, and December 22, 2023, with the Drug Identification Number 02410702. ZAXINE® is distributed in Canada in 550 mg tablets by Lupin Canada.

The 436 Patent

12. The 436 Patent is valid and effective and will remain valid and effective until it expires. Plaintiff pleads and relies upon section 43(2) of the *Patent Act*.

13. The 436 Patent is and always has been eligible for listing on the Patent Register in respect of ZAXINE®.

14. Plaintiff pleads and relies upon the 436 Patent, a copy of which is attached as Schedule “A” to this Statement of Claim.

15. The 436 Patent is entitled “Use of Rifaximin for Treating Hepatic Encephalopathy”. The 436 Patent issued on August 27, 2019, from an application filed October 2, 2009. The 436 Patent claims priority to a United States Patent Application No. US 61/102,349 filed on October 2, 2008. The inventor of the 436 Patent is William Forbes.

16. The 436 Patent has been in full force and effect from its date of issue up to and including the date hereof. It will expire on October 2, 2029. The 436 Patent is presumed valid.

17. The 436 Patent contains 19 claims, which read as follows:

1. Use of rifaximin in the manufacture of a medicament for decreasing a subject's risk of a hepatic encephalopathy (HE) breakthrough episode, wherein the rifaximin is for administration daily to the subject for a period of 12 months or longer at a dose of 550 mg two times per day (BID), and wherein the breakthrough episode is defined as an increase of the Conn score to Grade ≥ 2 or an increase in Conn score of 1 and asterixis grade of 1 for subjects having a baseline Conn score of 0.
2. The use of claim 1, wherein the rifaximin is for administration to the subject as two dosage forms of 275 mg two times per day.
3. The use of claim 1, wherein the rifaximin is for administration to the subject for two to three years.
4. The use of claim 1, wherein the rifaximin is for administration daily to the subject until the subject's death.
5. The use of claim 1, wherein the rifaximin is for administration with lactulose.
6. The use of claim 1, wherein the rifaximin is for administration with one or more of Align®, alinia, lactulose, Pentasa®, cholestyramine, Sandostatin®, vancomycin, lactose, Amitiza®, Flagyl®, Zegerid®, Prevacid®, or

Miralax®.

7. The use of claim 1, wherein administration of rifaximin prevents an increase in Conn score of the subject.
8. The use of claim 1, wherein there is an increase in time to a first HE-related hospitalization of the subject.
9. The use of claim 1, wherein there is an increase in the time to development of spontaneous bacterial peritonitis (SBP) of the subject.
10. The use of claim 1, wherein there is a decrease in blood ammonia concentration from baseline after administration of rifaximin to the subject.
11. The use of claim 10, wherein the decrease in blood ammonia concentration from baseline to 170 days is 6 µg/dL.
12. The use of claim 1, wherein there is an increase in critical flicker frequency values from baseline after administration of rifaximin to the subject.
13. The use of claim 1, wherein there is a shift from baseline in asterixis grades over time after administration of rifaximin to the subject.
14. The use of claim 1, wherein there is a change from baseline in Chronic Liver Disease Questionnaire (CLDQ) scores over time after administration of rifaximin to the subject.
15. The use of claim 1, wherein there is a change from baseline in Epworth Sleepiness Scale scores over time after administration of rifaximin to the subject.
16. The use of claim 1, wherein the subject has a meld level of between 1 to 24.
17. The use of claim 1, wherein the subject has a meld level less than or equal to ten.
18. The use of claim 1, wherein the subject has a meld level between 11 and 18.
19. The use of claim 1, wherein the subject has a meld level between 19 and 24.

Apotex will infringe the claims of the 436 Patent

18. The making, constructing, using, importing, offering for sale, selling and exporting of APO-RIFAXIMIN in accordance with the Apotex ANDS will infringe each and every claim of the 436 Patent. The infringing activities will be carried out by Apotex directly or indirectly or by third parties authorized and induced by Apotex to infringe. Apotex knows that its influence will result in the acts of infringement by third parties. Without the influence of Apotex, these infringing acts of third parties would not occur.

19. Apotex or third parties authorized and induced by Apotex will position APO-RIFAXIMIN to be used instead of, and with comparable effect to, ZAXINE®. Physicians, other healthcare providers, payors, and patients will be led by Apotex or third parties authorized and induced by Apotex to believe that APO-RIFAXIMIN can be used in the same manner and for the same indications as ZAXINE®.

20. ZAXINE® is approved for the reduction in risk of overt HE recurrence in patients ≥ 18 years of age. The corresponding use of APO-RIFAXIMIN will infringe all of the claims of the 436 Patent.

21. In particular, physicians, other healthcare providers, payors and patients will be induced by Apotex or third parties authorized and induced by Apotex to prescribe, dispense, reimburse, and use APO-RIFAXIMIN for the reduction in risk of overt HE. Apotex is aware and intends that APO-RIFAXIMIN will be prescribed, dispensed, reimbursed, and used in this manner.

22. The making, constructing, using, importing, offering for sale, selling and exporting of APO-RIFAXIMIN will entail, in accordance with claim 1 of the 436 Patent:

- a) use of rifaximin in the manufacture of a medicament for decreasing a subject's risk of a hepatic encephalopathy (HE) breakthrough episode
- b) wherein the rifaximin is for administration daily to the subject for a

period of 12 months or longer at a dose of 550 mg two times per day (BID), and

- c) wherein the breakthrough episode is defined as an increase of the Conn score to Grade ≥ 2 Correct this or an increase in Conn score of 1 and asterixis grade of 1 for subjects having a baseline Conn score of 0

23. The making, constructing, using, importing, offering for sale, selling and exporting of APO-RIFAXIMIN will further entail, in accordance with claims 2 to 19 of the 436 Patent:

- a) rifaximin that is for administration to the subject as two dosage forms of 275 mg two times per day;
- b) rifaximin that is for administration to the subject for two to three years;
- c) rifaximin that is for administration daily to the subject until the subject's death;
- d) rifaximin that is for administration with lactulose;
- e) rifaximin that is for administration with one or more of Align®, alinia, lactulose, Pentasa®, cholestyramine, Sandostatin®, vancomycin, lactose, Amitiza®, Flagyl®, Zegerid®, Prevacid®, or Miralax®;
- f) administration of rifaximin that prevents an increase in Conn score of the subject;
- g) an increase in time to a first HE-related hospitalization of the subject;
- h) an increase in the time to development of spontaneous bacterial peritonitis (SBP) of the subject;
- i) a decrease in blood ammonia concentration from baseline after administration of rifaximin to the subject;

- j) a decrease in blood ammonia concentration from baseline to 170 days is 6 µg/dL;
- k) an increase in critical flicker frequency values from baseline after administration of rifaximin to the subject;
- l) a shift from baseline in asterixis grades over time after administration of rifaximin to the subject;
- m) a change from baseline in Chronic Liver Disease Questionnaire (CLDQ) scores over time after administration of rifaximin to the subject;
- n) a change from baseline in Epworth Sleepiness Scale scores over time after administration of rifaximin to the subject;
- o) that the subject has a meld level of between 1 to 24;
- p) that the subject has a meld level less than or equal to ten;
- q) that the subject has a meld level between 11 and 18; and
- r) that the subject has a meld level between 19 and 24.

24. Apotex, or third parties authorized and induced by Apotex, will position APO-RIFAXIMIN to be used instead of, and with comparable effect to, ZAXINE[®], thereby influencing physicians, other healthcare providers and patients (collectively “APO-RIFAXIMIN Users”) to use APO-RIFAXIMIN for the reduction in risk of overt HE in accordance with all of the claims of the 436 Patent. Apotex (or third parties authorized and induced by Apotex) will lead APO-RIFAXIMIN Users to believe that APO-RIFAXIMIN can be used in the same manner and for the same indications as ZAXINE[®].

25. Without Apotex’s influence (or the influence of third parties authorized and induced by Apotex), APO-RIFAXIMIN Users would not use APO-RIFAXIMIN in accordance with the claims of the 436 Patent. Apotex (or third parties authorized and

induced by Apotex) know that their influence will result in APO-RIFAXIMIN Users using APO-RIFAXIMIN for the reduction in risk of overt HE in accordance with each of the claims of the 436 Patent.

Plaintiff's Claimed Relief

26. Plaintiff claims declaratory and injunctive relief in accordance with section 6 and paragraph 7(1)(e) of the *Regulations*, subsection 57(1) of the *Patent Act*, subsection 55.1 of the *Patent Act*, and rule 64 of the *Federal Courts Rules*.

27. Unless Apotex is restrained by this Honourable Court, Apotex's infringement of the 436 Patent will cause damages to Plaintiff.

28. In the event that Apotex were to commit any act of infringement of any of the claims of the 436 Patent, Plaintiff reserves the right to amend this Statement of Claim to seek additional relief accordingly, and seek any and all relief available including under the Patent Act in respect of same, including without limitation a claim for damages or an accounting of Apotex's profits, at Plaintiff's election.

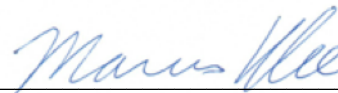
29. Plaintiff relies on the *Regulations*, the *Patent Act*, the *Federal Courts Act*, RSC 1985, c F-7, as amended; the *Federal Courts Rules*, SOR/98-106, as amended; the *Food and Drugs Act*, RSC 1985, c F-27, as amended; the *Food and Drugs Regulations*, CRC 1978, c 870, as amended; the *Canada Evidence Act*, RSC 1985 c C-5, amended; as well as such further and other grounds as counsel may advise and this Honourable Court may permit.

30. This action is not being proceeded with as a simplified action.

31. The amount of damages claimed exclusive of interest and costs exceeds \$50,000.00

32. Plaintiff proposes that this action be tried in Ottawa, Ontario.

May 22, 2026



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