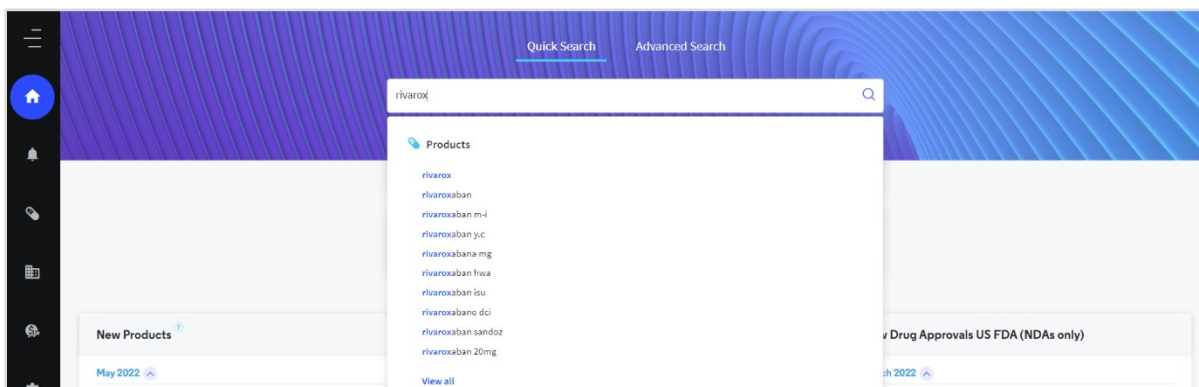


# US Paragraph IV Patent Challenges

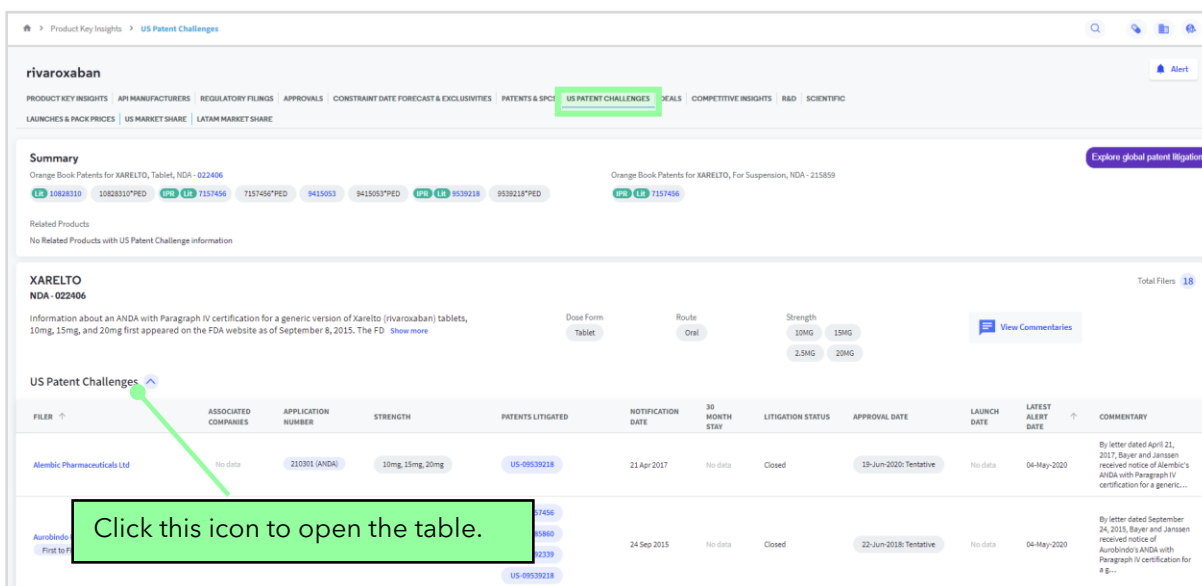
Learn how to find the Paragraph IV Challenge Commentaries in Cortellis Product Intelligence. The Cortellis Product Intelligence Research Team monitors and collects information on Paragraph IV Patent Challenges and updates the content daily.

Example: Find the US Patent Challenge commentary for rivaroxaban.

1. Use the **Quick Search** tool to find the rivaroxaban record.



2. In the product record click the **US Patent Challenges** Tab. The streamlined design allows you to open the table and view data on the Filters, the patents litigated, the approval date and more.
3. Click the **View Commentaries** button to open a pop up of an exportable PIV Patent Challenge Commentary.



**Summary**

Orange Book Patents for XARELTO, Tablet, NDA - 022406

10828310 | 10828310\*PED | **EP 18 7157456** | 7157456\*PED | 9415053 | 9415053\*PED | **EP 18 9530218** | 9530218\*PED | **EP 18 7157456**

Related Products

No Related Products with US Patent Challenge information

**XARELTO**  
NDA - 022406

Information about an ANDA with Paragraph IV certification for a generic version of Xarelto (rivaroxaban) tablets, 10mg, 15mg, and 20mg first appeared on the FDA website as of September 8, 2015. The FD [Show more](#)


Dose Form: Tablet, Route: Oral, Strength: 10MG, 15MG, 2.5MG, 20MG

**US Patent Challenges**

FILER	ASSOCIATED COMPANIES	APPLICATION NUMBER	STRENGTH	PATENTS LITIGATED	NOTIFICATION DATE	30 MONTH STAY	LITIGATION STATUS	APPROVAL DATE	LAUNCH DATE	LATEST ALERT DATE	COMMENTARY
<a href="#">Aurobindo Pharmaceuticals Ltd</a>	No data	210301 (ANDA)	10mg, 15mg, 20mg	<a href="#">US-09539218</a>	21 Apr 2017	No data	Closed	19-Jun-2020: Tentative	No data	04-May-2020	By letter dated April 21, 2017, Bayer and Janssen received notice of Aurobindo's ANDA with Paragraph IV certification for a generic...
<a href="#">Aurobindo Pharmaceuticals Ltd</a>	No data	210301 (ANDA)	10mg, 15mg, 20mg	<a href="#">US-09539218</a>	24 Sep 2015	No data	Closed	22-Jun-2018: Tentative	No data	04-May-2020	By letter dated September 24, 2015, Bayer and Janssen received notice of Aurobindo's ANDA with Paragraph IV certification for a generic...

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janssen

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## XARELTO NDA 022406

Information about an ANDA with Paragraph IV certification for a generic version of Xarelto (rivaroxaban) tablets, 10mg, 15mg, and 20mg first appeared on the FDA website as of September 8, 2015. The FDA reports a submission date of July 1, 2015, which was the first day an ANDA could have been submitted for a rivaroxaban product. The New Chemical Entity exclusivity for rivaroxaban expired on July 1, 2016. The FDA reports eight ANDAs for generic versions of Xarelto tablets, 10mg, 15mg, and 20mg were filed on the first day possible and may share eligibility for the 180-day generic drug exclusivity. Information about an ANDA with Paragraph IV certification for a generic version of Xarelto tablets, 2.5mg first appeared on the FDA website as of December 3, 2018. The FDA reports a submission date of November 19, 2018. According to the FDA, four ANDAs for generic versions of Xarelto tablets, 2.5mg were filed on the same day and may share eligibility for the 180-day generic drug exclusivity for that strength.

Alembic Pharmaceuticals Ltd: 210301 (ANDA)

Search terms are highlighted.

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By letter dated April 21, 2017, Bayer and **Janssen** received notice of Alembic's ANDA with Paragraph IV certification for a generic version of Xarelto tablets. On June 2, 2017, Bayer and **Janssen** filed a patent infringement suit against Alembic in the U.S. District Court for the District of Delaware in response to Alembic's ANDA. Bayer and **Janssen** alleged infringement of U.S. Patent 9,539,218. <sup>1</sup> On November 13, 2017, the Delaware court consolidated the Alembic, Aurobindo, Breckenridge, InvaGen, Lupin, Micro Labs, Mylan, Sigmapharm, Taro, and Torrent cases concerning U.S. Patent 9,539,218. <sup>2</sup> On June 15, 2018, the Delaware court stayed the case concerning U.S. Patent 9,539,218 with respect to Alembic and the parties agreed to be bound by any final judgment on the merits in the remaining consolidated action. <sup>3</sup> Trial in the consolidated case concerning U.S. Patent 9,539,218 began on April 5, 2019. <sup>4</sup> On March 2, 2020, the parties to the Lupin litigation stipulated to the dismissal of the matter with prejudice. <sup>5</sup> To our knowledge, no patent settlement terms have been disclosed. The FDA tentatively approved Alembic's ANDA on June 19, 2020. Alembic holds a DMF for rivaroxaban.

1: Bayer Intellectual Property GmbH et al. v. Alembic Pharmaceuticals Limited et al., U.S. District Court, D. Delaware, Case 1:17-cv-00675, 2017-06-02

2: Bayer Intellectual Property GmbH et al. v. Taro Pharmaceutical Industries Ltd. et al., U.S. District Court, D. Delaware, Case 1:17-cv-00462, 2017-11-13

3: Bayer Intellectual Property GmbH et al. v. Taro Pharmaceutical Industries Ltd. et al., U.S. District Court, D. Delaware, Case 1:17-cv-00462, 2018-06-15

4: Bayer Intellectual Property GmbH et al. v. Taro Pharmaceutical Industries Ltd. et al., U.S. District Court, D. Delaware, Case 1:17-cv-00462, 2019-04-05

5: Bayer Intellectual Property GmbH et al. v. Taro Pharmaceutical Industries Ltd. et al., U.S. District Court, D. Delaware, Case 1:17-cv-00462, 2020-03-02

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