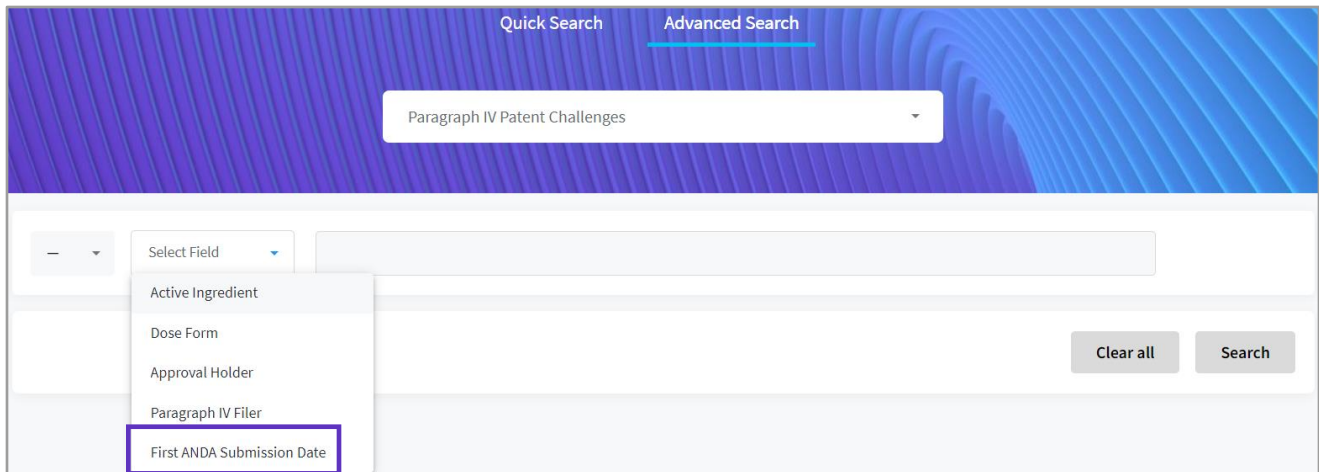


# Cortellis Generics Intelligence

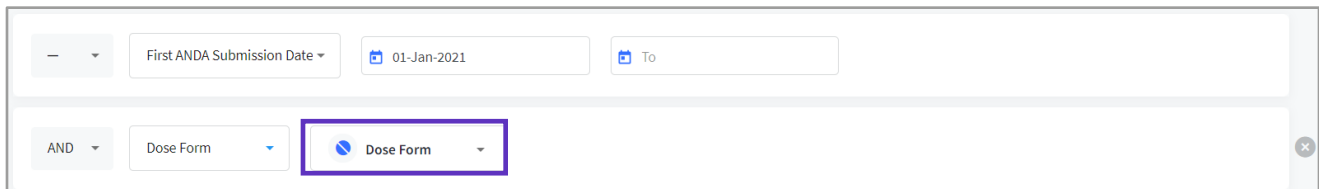
## Find recent patent challenges in the USA

Paragraph IV certifications and Patent Challenges in the USA are available in product records in *Cortellis Generics Intelligence*. They can be searched by product name, submission date and other fields from *Advanced Search*. This example shows you how to find recent patent challenges in the USA filed on products formulated as tablets.

1. Once in *Advanced Search*, select 'Paragraph IV Patent Challenges' from the search box at the top and then 'First ANDA Submission Date' from the menu below.

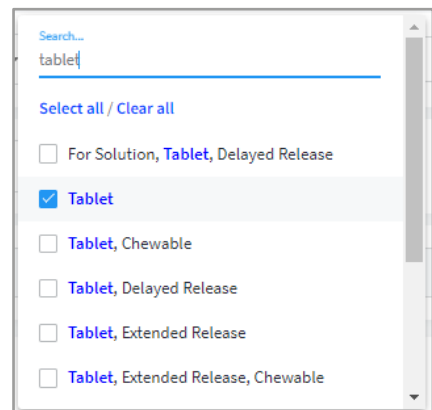


2. Enter starting date or time range (eg. After 1<sup>st</sup> Jan 2020) and add 'Dose Form' as an additional field.



3. Look up and select 'Tablet' from the drop-down menu in 'Dose Form'.

4. Click  to retrieve results.



5. Results table is displayed next showing API names, PIV filers, dose form/strength and other details.

Advanced Search > PIV Patent Challenges

Advanced Search Results

Customize Columns ? Export

Hide/Display columns and download this table to share with colleagues by using buttons at the top left.

Showing 1-10 of 24

ACTIVE INGREDIENT	APPROVAL NUMBER	APPROVAL HOLDER	APPROVAL DATE	PARAGRAPH IV FILER	DOSE FORM	STRENGTH	US PATENT CHALLENGES PAGE
brivaracetam	205836	UCB Inc	12-May-2016	Aurobindo Pharma Ltd Lupin Ltd ***	Tablet	25MG	<a href="#">View Challenges</a>
venetoclax	208573	AbbVie Inc	11-Apr-2016	Dr Reddy's Group Alembic Pharmaceutica...	Tablet	50MG	<a href="#">View Challenges</a>
obeticholic acid	207999	Intercept Pharmaceuticals L...	27-May-2016	Lupin Ltd Dr Reddy's Group ***	Tablet	5MG	<a href="#">View Challenges</a>

6. Click 'View Challenges' on the right to navigate directly to *US Patent Challenges* tab in *venetoclax* product record to identify specific patents affected, for example.

venetoclax

PRODUCT KEY INSIGHTS | API MANUFACTURERS | REGULATORY FILINGS | APPROVALS | CONSTRAINT DATE | PATENTS & SPCS | **US PATENT CHALLENGES** | DEALS | COMPETITIVE INSIGHTS | R&D | SCIENTIFIC

LAUNCHES & PACK PRICES | US MARKET SHARE | LATAM MARKET SHARE

Summary

Orange Book Patents for VENCLEXTA, Tablet, NDA - 208573

10730873 Lit 8546399 Lit 8722657 Lit 9174982 9539251

Related Products

No Related Products with US Patent Challenge information

VENCLEXTA  
NDA - 208573

Total Filers 2

Information about an ANDA with Paragraph IV certification for a generic version of Venclexta (venetoclax) tablets, 10mg, 50mg, and 100mg first appeared on the FDA website as of June 1, 2020. The FDA r [Show more](#)

Dose Form: Tablet | Route: Oral | Strength: 100MG, 10MG, 50MG

[View Commentaries](#)

US Patent Challenges

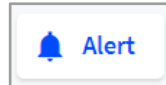
Clicking 'View Commentaries' opens a new window providing expert insights on the litigation process.

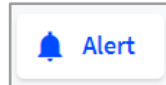
7. Click 'US Patent Challenges' on the left to display application number, notification dates, litigation status and more details.

US Patent Challenges

FILER	ASSOCIATED COMPANIES	APPLICATION NUMBER	STRENGTH	PATENTS LITIGATED	NOTIFICATION DATE	30 MONTH STAY	LITIGATION STATUS	APPROVAL DATE	LAUNCH DATE	COMMENTARY
Alembic Pharmaceuticals Ltd First to File Assumed	No data	214747 (ANDA)	10mg, 50mg, 100mg	US-08722657	16 Jun 2020	Oct 2023	Ongoing	Filed	No data	On June 16, 2020, AbbVie and Genentech received notification of Alembic's ANDA with Paragraph IV certification for a generic ver...
Dr Reddy's Group First to File Assumed	No data	214733 (ANDA)	10mg, 50mg, 100mg	US-08546399 US-08722657 US-09174982	08 Jun 2020	Oct 2023	Ongoing	Filed	No data	On June 8, 2020, AbbVie and Genentech received notification of Dr. Reddy's ANDA with Paragraph IV certification for a generic ver...

8. *US Patent Challenges* tab in *Cortellis Generics Intelligence* is updated within 24-48 hrs after news have been announced. Email alerts can be set up to notify you when new information is available. Therefore, it is highly



recommended to set up an  from the bell icon at the top right in the product record of interest, as shown next:

### Content Update Alert ×

- New US FDA Orange Book Approval
- Change to existing US FDA Orange Book Approval
- US FDA Biologics Approvals
  - New US FDA Biologics Approval
  - Change to existing US FDA Biologics Approval
- Constraint Date Forecast ^
  - Change in Constraint Date Forecast
- SPCs ^
  - New SPC
  - Change to existing SPC
- US Patent Challenges ^
  - New US Patent Challenge
  - Change to existing US Patent Challenge

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Alerts allow you to keep track of new and existing patent challenges in the USA.

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