



# Cortellis Product Intelligenceを使って、 ジェネリックの上市を予測・計画する

# Cortellis Product Intelligenceを使って、ジェネリックの上市を予測・計画する

- 必要な情報

- 医薬品の独占権がいつ消失するか？
- 他にUSパテントチャレンジを申請している企業はいるか？

- 共通の課題

- ジェネリック医薬品発売時期の予測に必要なデータが不十分
- 新製品や競合他社製品の評価に必要なデータが不十分
- 不正確なデータや、不十分な製品選択による売り上げの損失

## 3ステップ°

Cortellis Product  
Intelligenceを使って  
必要な情報を収集

1. 異なる市場においてジェネリックが発売される予定日を確認する
2. ジェネリック参入を阻む独占権を理解する
3. 米国において申請されたパテントチャレンジを探す

# 1.異なる市場（例：ベルギー、イタリア、米国）においてジェネリックが発売される予定日を確認する

調べたい医薬品のProductレコードを開いたら[Constraint Date Forecast & Exclusivities] のタブに移動し、Constraint Date Forecast\*を確認する

The screenshot shows the 'apixaban' product page with the 'Constraint Date Forecast & Exclusivities' tab selected. The table below displays the data for various countries.

COUNTRY/TERRITORY ↑	CONSTRAINT DATE ⓘ ↑	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
Malta	20-May-2021	It is based on the expiry date of Data + Marketing Exclusivity	Data exclusivity in Malta has expired.
Ireland	19-May-2026	It is based on the expiry date of an SPC	Data exclusivity in Ireland has expired. The earliest SPC in Ireland expires on 19-May-2026.
Netherlands	19-May-2026	It is based on the expiry date of an SPC	Data exclusivity in Netherlands has expired. The earliest SPC in Netherlands expires on 19-May-2026.
Sweden	19-May-2026	It is based on the expiry date of an SPC	Data exclusivity in Sweden has expired. The earliest SPC in Sweden expires on 19-May-2026.
United Kingdom	19-May-2026	It is based on the expiry date of an SPC	Data exclusivity in United Kingdom has expired. The earliest SPC in United Kingdom expires on 19-May-2026.

\* **Constraint Date Forecast**（CDF）は、35を超える市場で製品が独占権を失うと予想される時期を予測します。この日付は、特定の国における特定の製品の特許、市場独占権、およびデータ独占権を考慮して算出されます。CDFはガイドラインとしての参考情報となりますので、確実な日付として解釈することはできない点をご注意ください。

## 2. ジェネリック参入を阻む独占権を理解する

フィルターで調べたい国を選択し、独占権（Exclusivities）やその消失日を確認する

**Constraint Date Forecast & Exclusivities** ⓘ

Filters Country/Territory

Custom

Rows per page: 10 1-10 of 38

COUNTRY/TERRITORY	CONSTRAINT DATE ⓘ ↑	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
Malta	May-2021	It is based on the expiry date of Data + Marketing Exclusivity	Data exclusivity in Malta has expired.
Ireland	May-2026	It is based on the expiry date of an SPC	Data exclusivity in Ireland has expired. The earliest SPC in Ireland expires on 19-May-2026.
Netherlands	May-2026	It is based on the expiry date of an SPC	Data exclusivity in Netherlands has expired. The earliest SPC in Netherlands expires on 19-May-2026.
Sweden	19-May-2026	It is based on the expiry date of an SPC	Data exclusivity in Sweden has expired. The earliest SPC in Sweden expires on 19-May-2026.
United Kingdom	19-May-2026	It is based on the expiry date of an SPC	Data exclusivity in United Kingdom has expired. The earliest SPC in United Kingdom expires on 19-May-2026.

# 3. 米国において申請されたパテントチャレンジを探す

[US Patent Challenges] のタブに移動し、米国におけるパテントチャレンジを確認する

**apixaban**

PRODUCT KEY INSIGHTS | API MANUFACTURERS | REGULATORY FILINGS | APPROVALS | CONSTRAINT DATE FORECAST & EXCLUSIVITIES | PATENTS & SPCS | **US PATENT CHALLENGES** | GLOBAL LITIGATION | DEALS | COMPETITIVE INSIGHTS | R&D | SCIENTIFIC | LAUNCHES & PACK PRICES

US MARKET SHARE | LATAM MARKET SHARE

### Summary

Orange Book Patents for ELIQUIS, Tablet, NDA - 202155

IPR Lit 6967208 | IPR Lit 9326945

Related Products

No Related Products with US Patent Challenge information

### ELIQUIS NDA - 202155

Information about an ANDA with Paragraph IV certification for a generic version of Eliquis (apixaban) tablets, 2.5 mg and 5 mg, first appeared on the FDA website as of March 13, 2017. The FDA reports [Show more](#)

Dose Form: Tablet | Route: Oral | Strength: 2.5MG, 5MG

Total Filers 25

[View Commentaries](#)

### 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
Amneal Pharmaceuticals First to File: Assumed	No data	209810 (ANDA)	2.5mg, 5mg	US-09326945	06 Mar 2017	No data	Closed	19-Aug-2020: Tentative	No data	01-May-2020	On March 6, 2017, Bristol-Myers Squibb and Pfizer received notification of Impax's ANDA with Paragraph IV certification for a generic version of Eliquis tablets. On April 10, 2017, Bristol-Myers Squibb and Pfizer filed a patent infringement suit against Impax in the U.S. District Court for the District of Delaware in response to Impax's ANDA. The plaintiffs alleged infringement of U.S. Patent 9,326,945. <sup>1</sup> On June 28, 2018, the parties to the Impax action stipulated to the dismissal of the matter without prejudice. <sup>2</sup> To our knowledge, no settlement terms have been disclosed.

### ELIQUIS NDA 202155

Information about an ANDA with Paragraph IV certification for a generic version of Eliquis (apixaban) tablets, 2.5 mg and 5 mg, first appeared on the FDA website as of March 13, 2017. The FDA reports a filing date of December 28, 2016, which was the first day an ANDA could have been submitted for an apixaban product. The New Chemical Entity exclusivity for apixaban expired on December 28, 2017. The FDA reports 25 ANDAs for generic versions of Eliquis tablets were filed on the first day possible and may be eligible for the 180-day generic drug exclusivity. Bristol-Myers Squibb expects to lose exclusivity for Eliquis tablets in November 2026. <sup>1</sup>

<sup>1</sup>: Form 10-K, Bristol-Myers Squibb Company, 2019-02-25

### Amneal Pharmaceuticals: 209810 (ANDA)

On March 6, 2017, Bristol-Myers Squibb and Pfizer received notification of Impax's ANDA with Paragraph IV certification for a generic version of Eliquis tablets. On April 10, 2017, Bristol-Myers Squibb and Pfizer filed a patent infringement suit against Impax in the U.S. District Court for the District of Delaware in response to Impax's ANDA. The plaintiffs alleged infringement of U.S. Patent 9,326,945. <sup>1</sup> On June 28, 2018, the parties to the Impax action stipulated to the dismissal of the matter without prejudice. <sup>2</sup> To our knowledge, no settlement terms have been disclosed.

<sup>1</sup>: Bristol-Myers Squibb Company et al. v. Impax Laboratories, Inc., U.S. District Court, D. Delaware, Case 1:17-cv-00403, 2017-04-10  
<sup>2</sup>: Bristol-Myers Squibb Company et al. v. Impax Laboratories, Inc., U.S. District Court, D. Delaware, Case 1:17-cv-00403, 2018-06-28

### Apotex Inc: 210091 (ANDA)

On March 13, 2017, Bristol-Myers Squibb and Pfizer received notification of Apotex's ANDA with Paragraph IV certification for a generic version of Eliquis tablets. On April 10, 2017, Bristol-Myers Squibb and Pfizer filed a patent infringement suit against Apotex in the U.S. District Court for the District of Delaware in response to Apotex's ANDA. The plaintiffs alleged infringement of U.S. Patent 6,413,980, U.S. Patent 9,326,945, and U.S. Patent 9,326,945. <sup>1</sup> On January 16, 2018, the parties to the Apotex action stipulated to the dismissal of the matter without prejudice. <sup>2</sup> To our knowledge, no settlement terms have been disclosed.

クリックするとパテント  
チャレンジの詳細を確認  
いただけます。