

# Cortellis Product Intelligence Clarivate Training Webinar

## Cortellis Product Intelligenceによる特許情報の収集

Clarivate Life Sciences & Healthcare

Apr 24th. 2025



# 本日の内容

- Cortellis Product Intelligence 概要
- 利用事例
  - ジェネリック開発候補品が参入可能になる時期の目安を確認
  - 米国における特許出願と独占権の調査
  - 米国における承認および承認申請情報の確認
  - Paragraph IV Patent Challenge情報の収集
  - 医薬品ごとの訴訟状況の全体像を把握
- ユーザサポートと開発ロードマップのご案内

# 原薬・ジェネリック ビジネスの全容把握

- 市場実績、特許、および製造データに関する最適な情報源
- 迅速かつ十分な情報に基づいたビジネス上の意思決定を可能に
- 全ての情報を一元化した信頼できる単一のソリューション

Cortellis Product Intelligence



## 85,000社以上

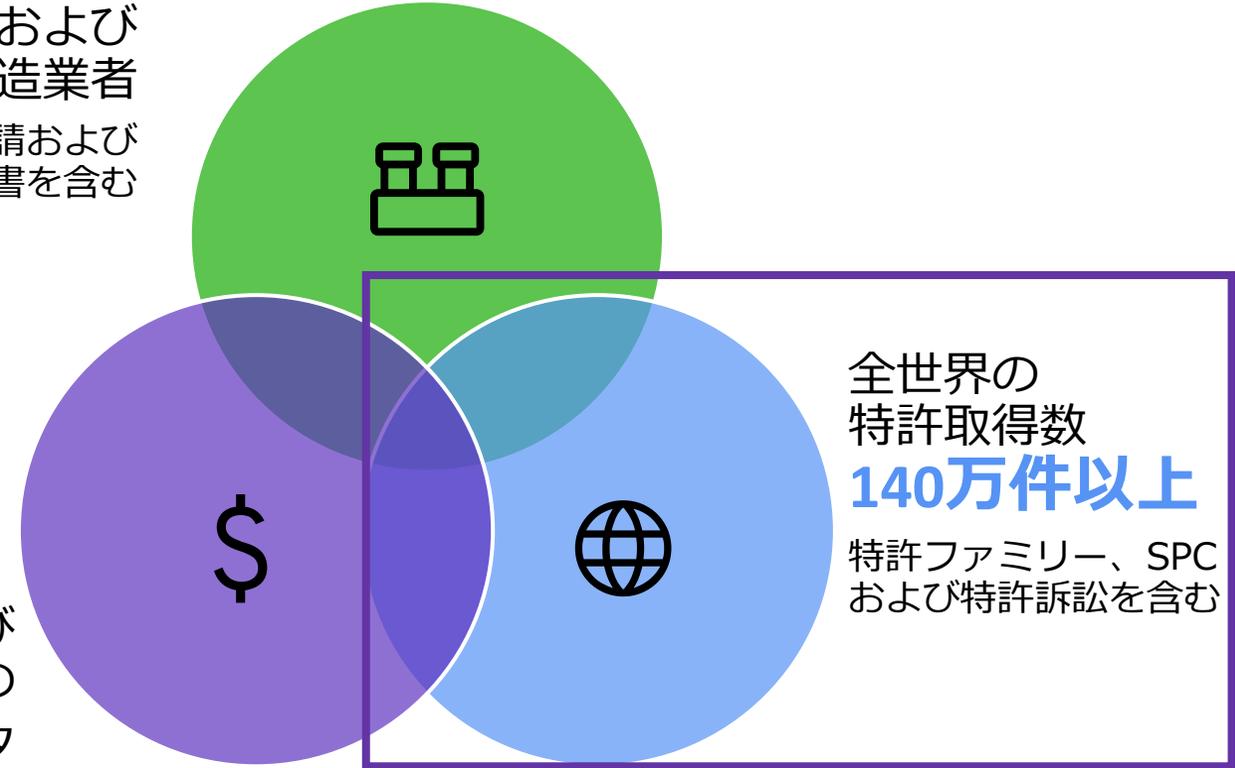
原薬製造業者および  
製剤製造業者

規制当局への申請および  
査察証明書を含む

売上高および  
消費量 (kg) の  
**グローバル**データ

上市、パッケージ価格、  
市場シェアを含む

※ご利用はGlobalまたはPremium  
Moduleご利用のお客様に限定されます。



# ジェネリック 参入予測日

## • Constraint Date Forecast

- 36カ国についてジェネリック参入可能日を予測
- 各国のマーケット状況に合わせ、特許期限満了日、期間延長、市場優先権、データ保護期間、再審査期間など加味して後発品参入日を算出
- 複雑な独占権の情報収集と分析を効率化し、幅広い初期スクリーニングを可能にします

COUNTRY/TERRITORY ↑	CONSTRAINT DATE ↑	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
USA	30-Jun-2020	It is based on the expiry date of a Product Patent	No data
Canada	12-Jul-2020	It is based on the expiry date of Data + Marketing Exclusivity	No data
Malta	05-Sep-2022	It is based on the expiry date of Data + Marketing Exclusivity	Data + Marketing exclusivity in Malta expires on 05-Sep-2022, 8+2 years from the first marketing authorization in EEA on 05-Sep-2012.
Poland	05-Sep-2022	It is based on the expiry date of Data + Marketing Exclusivity	Data + Marketing exclusivity in Poland expires on 05-Sep-2022, 8+2 years from the first marketing authorization in EEA on 05-Sep-2012.
Cyprus	29-Jun-2025	It is based on the expiry date of an SPC	The earliest SPC in Cyprus expires on 29-Jun-2025. Data + Marketing exclusivity in Cyprus expires on 05-Sep-2022, 8+2 years from the first marketing authorization in EEA on 05-Sep-2012.
France	29-Jun-2025	It is based on the expiry date of an SPC	Data + Marketing exclusivity in France expires on 05-Sep-2022, 8+2 years from the first marketing authorization in EEA on 05-Sep-2012. The earliest SPC in France expires on 29-Jun-2025.

Constraint Date Forecast  
(国毎のジェネリック参入可能予測日)

有効な独占権

# 活用事例のご紹介



# 1. ジェネリックが参入可能になる時期の目安を把握したい

Product Key Insights > Constraint Date Forecast & Exclusivities

Constraint Dateタブ選択

enzalutamide

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

Constraint Date Forecast & Exclusivities

Filters Country/Territory (14)

一覧を国で絞り込み

有効な独占権

Constraint Dateの根拠

COUNTRY/TERRITORY	CONSTRAINT DATE	CONSTRAINT DATE RATIONALE	EXCLUSIVITIES
Bulgaria	25-Jun-2028	It is based on the expiry date of an SPC	The earliest SPC in Bulgaria expires on 25-Jun-2028. Data exclusivity in Bulgaria has expired.
Croatia	25-Jun-2028	It is based on the expiry date of an SPC	Data exclusivity in Croatia has expired. The earliest SPC in Croatia expires on 25-Jun-2028.
Czech Republic	25-Jun-2028	It is based on the expiry date of an SPC	The earliest SPC in Czech Republic expires on 25-Jun-2028. Data exclusivity in Czech Republic has expired.
Estonia	25-Jun-2028	...	The earliest SPC in Estonia expires on 25-Jun-2028.

国毎のジェネリック参入可能予測日

## Constraint Date Forecast

- 36カ国についてジェネリック参入可能日を予測
- 各国のマーケット状況に合わせ、特許期限満了日、特許期間延長、市場優先権、SPC、データ保護期間、再審査期間、その他の独占権（例：Pediatric exclusivity）など加味して後発品参入日を予測

※ 特許や各種独占権を統合することで、ジェネリック開発候補品検討やジェネリック参入のインパクト分析をしやすくする指標です。「権利満了の確定日ではない」ことにご注意ください。



## 2. 米国における特許出願状況と独占権を調べたい

Product Key Insights > Patents & SPCs

Patents & SPCsタブを選択

enzalutamide

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

Worldwide Patent Families

Patents by Authority

SPCs

US Patents & Exclusivities Associated with Approvals

US Patents & Exclusivities Associated with Approvalsタブを選択

US Patents & Exclusivities Associated with Approvals

Filters: Filing/Approval Number | Dose Form | Publication Number | **Exclusivity Type**

独占権のタイプで絞り込み

Orange Book 特許情報

Customize Columns | Export

Rows per page: 10 | 1-10 of 17 | 1 2

ACTIVE INGREDIENT	DE NAME	FILING/APPROVAL NUMBER	EXCLUSIVITY TYPE	EXCLUSIVITY EXPIRY DATE	APPROVAL HOLDER	DOSE FORM	PUBLICATION NUMBER	PATENT TYPE	ORANGE BOOK PATENT EXPIRY DATE
enzalutamide	NDI	213674-002	I-926	17-Nov-2026	Astellas Pharma Inc	Tablet	None reported	None reported	None reported
enzalutamide	NDI			None reported	Astellas Pharma Inc	Tablet	9126941	Constraining Formulation	15-May-2026
enzalutamide	NDI	213674-002	None reported	None reported	Astellas Pharma Inc	Tablet	12161628	Component of Combinat... Constraining	23-Feb-2037
enzalutamide	NDI	213674-002	None reported	None reported	Astellas Pharma Inc	Tablet	11839689	Constraining Formulation	11-Sep-2033

独占権タイプと失効日



### 3. 米国における承認および承認申請情報を整理したい

enzalutamide Alerts Bookmark

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

Worldwide Approvals | First Marketing Authorization Details\* | **US Filings & Approvals**

US Filings & Approvals **米国における承認および承認申請情報** FDA Bioequivalence Information US Patents & Exclusivities Associated with Approvals

Filters | Customize Columns | Export Rows per page: 10 | 1-10 of 17

TRADE NAME ↑	APPROVAL DATE ↑	APPROVAL STATUS ↑	FILING/APPROVAL TYPE ↑	US PATENT CHALLENGES ↑	ACTIVE INGREDIENT ↑	DOSE FORM ↑	ROUTE OF ADMINISTRATION ↑	STRENGTH ↑	NUMBER ↑
ENZALUTAMIDE	22-Apr-2022	Discontinued	ANDA	None reported	enzalutamide	Capsule	Oral	40MG	209645-001
XTANDI	31-Aug-2012	Approved - RX	NDA	PIV	enzalutamide	Capsule	Oral	40MG	203415-001
XTANDI	04-Aug-2020	Approved - RX	NDA	PIV	enzalutamide	Tablet	Oral	40MG	213674-001
XTANDI	04-Aug-2020	Approved - RX	NDA	PIV	enzalutamide	Tablet	Oral	80MG	213674-002
ENZALUTAMIDE 40MG	13-Jul-2023	Tentative	ANDA	None reported	enzalutamide	Capsules	Oral	No data	211465-000

Patent Challengeフラグ



# 4. 米国のParagraph IV Patent Challenge情報を取得したい

enzalutamide

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

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

US Patent Challenges タブを選択

Summary

Orange Book Patents for XTANDI, Capsule, NDA - 203415

Orange Book Patents for XTANDI, Tablet, NDA - 213674

Lit 12161628 Lit 7709517 Lit 8183274 Lit 9126941

Lit 11839689 Lit 12161628 Lit 7709517 Lit 8183274 Lit 9126941

Related Products

No Related Products with US Patent Challenge information

選択したPatentの詳細を表示

Patent Details

Detail and Information

Publication Number: US-09126941

Primary Patent Number: WO-2006124118, WO-2007127010

Publication Country/Territory: USA

Application Date: 17-Apr-2012

Patent Title: Treatment of hyperproliferative disorders with diarylhydantoin compounds

Priority Country/Territory: USA

Priority Date: 13-May-2005

Patent Holder: University of California

Actions: Androgen receptor antagonist

Indications: Breast tumor, Cancer, Ovary tumor, Prostate hyperplasia, Prostate tumor

Technologies: Oral formulation

Opponent/Infringer: No data

Annotations for Patent Family

US-09126941: This patent describing the treatment of hyperproliferative disorders with diarylhydantoin compounds including enzalutamide (MDV-3100) was granted initially granted as US8658681 in February 2014. Enzalutamide wa... Show more

WO-2006124118: No annotation available

WO-2007127010: No annotation available

Active Ingredients Covered in the Primary Patent

enzalutamide - Constraining

enzalutamide - Formulation

enzalutamide - New use

enzalutamide - Product

Expiry Information

enzalutamide

15-May-2026: Based on priority date

USA

Publication History

US-08658681: 25-Feb-2014: B2 - Reexamination Certificate Second Reexamination

※US Patent Challengesは、「GlobalおよびPremium」モジュールをご利用のお客様限定のコンテンツとなります。



# 4. 米国のParagraph IV Patent Challenge情報を取得したい

記載内容の検索  
と解説文の出力

**XTANDI**  
NDA -203415

Information about an ANDA with Paragraph IV certification for a generic version of Xtandi (enzalutamide) capsules, 40mg, first appeared on the FDA website as of November 4, 2016. The FDA reports a sub [show more](#)

Dose Form: Capsule | Route: Oral | Strength: 40MG

[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
Apotex Inc First to File: Assumed	No data	209645 (ANDA)	40mg	US-07709517 US-08183274 US-09126941	02 Nov 2016	No data	Closed	22-Apr-2022: Discontinued	No data	29-Sep-2023	On November 2, 2016, Astellas and the Regents of the University of California received notice of the Apotex ANDA with Paragraph IV...
Aurobindo Pharma Ltd	No data	211465 (ANDA)	40mg	US-07709517 US-08183274 US-09126941	13 Apr 2018	No data	Closed		No data	02-Nov-2023	On April 13, 2018, Astellas and the Regents of the University of California received notice of the Eugia ANDA with Paragraph IV...
Hetero Group	No data	220025 (ANDA)	40mg	US-07709517 US-08183274 US-11839689	18 Nov 2024	May 2027	Ongoing	Filed	No data	31-Jan-2025	By letter dated November 18, 2024, Astellas and the Regents of the University of California received notice of the Ascent Pharmaco...

解説を開く

Export

## XTANDI NDA 203415

Information about an ANDA with Paragraph IV certification for a generic version of Xtandi (enzalutamide) capsules, 40mg, first appeared on the FDA website as of November 4, 2016. The FDA reports a submission date of August 31, 2016, which was the first day an ANDA could have been submitted for an enzalutamide product. The New Chemical Entity exclusivity for enzalutamide expired on August 31, 2017. The FDA reports three ANDAs with Paragraph IV certification for generic versions of Xtandi capsules were filed on the first day possible and may share eligibility for the 180-day generic drug exclusivity.

### Apotex Inc: 209645 (ANDA)

On November 2, 2016, Astellas and the Regents of the University of California received notice of the Apotex ANDA with Paragraph IV certification for a generic version of Xtandi capsules. On December 9, 2016, Astellas, Medivation, and the Regents of the University of California filed a patent infringement suit against Apotex in the U.S. District Court for the District of Delaware in response to the Apotex ANDA. The plaintiffs alleged infringement of U.S. Patent 7,709,517, U.S. Patent 8,183,274, and U.S. Patent 9,126,941. <sup>1</sup> That case was subsequently consolidated with others under an earlier action concerning Actavis's ANDA for a generic version of Xtandi capsules. <sup>2</sup> On July 19, 2018, the case was dismissed with respect to Apotex after the plaintiffs and Apotex reached an agreement to settle their dispute. <sup>3</sup> To our knowledge, no settlement terms have been disclosed. The FDA approved the Apotex ANDA on April 22, 2022.

1: Astellas Pharma Inc. et al. v. Apotex Inc. et al., U.S. District Court, D. Delaware, Case 1:16-cv-01166, 2016-12-09  
 2: Astellas Pharma Inc. et al. v. Actavis Laboratories FL, Inc. et al., U.S. District Court, D. Delaware, Case 1:16-cv-01120, 2017-04-26  
 3: Astellas Pharma Inc. et al. v. Actavis Laboratories FL, Inc. et al., U.S. District Court, D. Delaware, Case 1:16-cv-01120, 2018-07-19

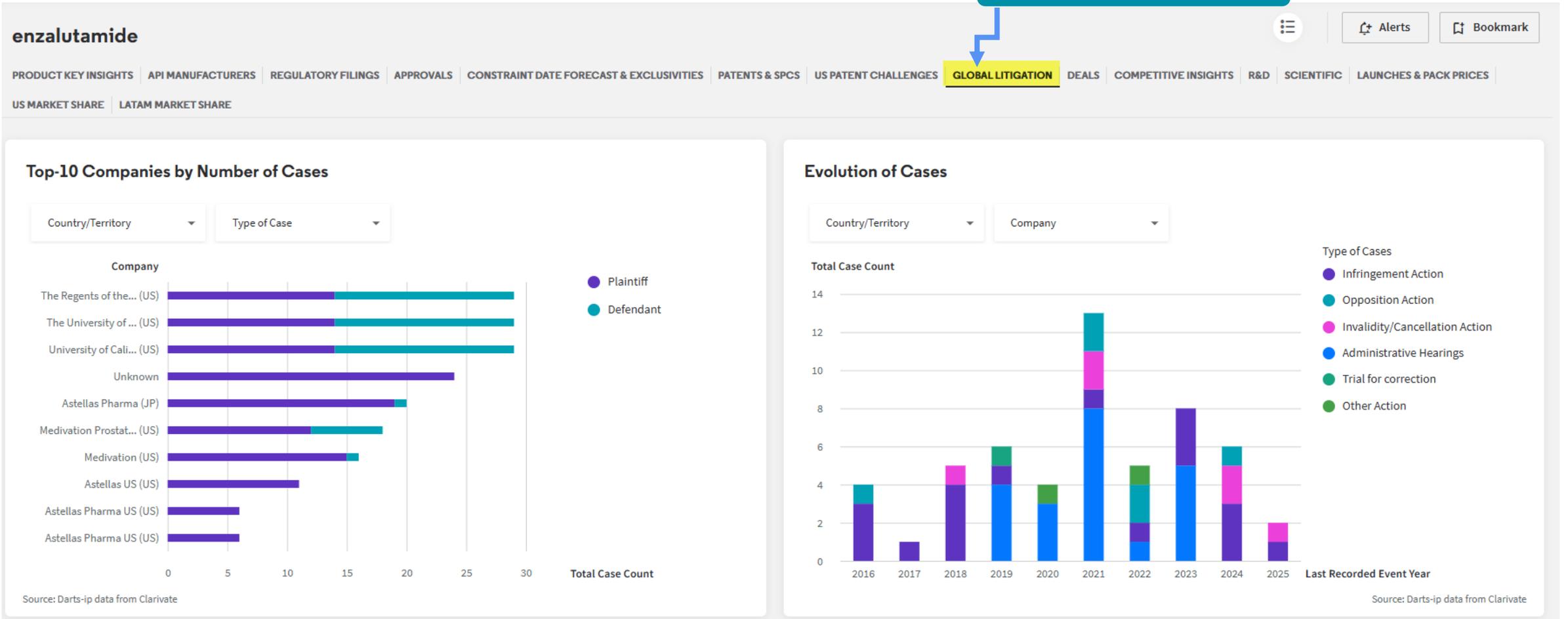
### Aurobindo Pharma Ltd: 211465 (ANDA)

On April 13, 2018, Astellas and the Regents of the University of California received notice of the Eugia ANDA with Paragraph IV certification for a generic version of Xtandi capsules. On May 17, 2018, Astellas, Medivation, and the Regents of the University of California filed a patent infringement suit against Eugia Pharma and Aurobindo in the U.S. District Court for the District of Delaware in response to the Eugia ANDA. The plaintiffs alleged infringement of U.S. Patent 7,709,517, U.S. Patent 8,183,274, and U.S. Patent 9,126,941. <sup>1</sup> On September 5, 2019, the case was dismissed after the parties reached an agreement to settle their dispute. <sup>2</sup> To our knowledge, no settlement terms have been disclosed. Eugia's ANDA has been tentatively approved more than once, most recently on July 13, 2023.



## 5. 全世界の訴訟状況の全体像を把握したい

Global Litigationタブ選択



※Global Litigationは、「GlobalおよびPremium」モジュールをご利用のお客様限定のコンテンツとなります。



## 5. 全世界の訴訟状況の全体像を把握したい

### 訴訟リスト

- Plaintiff / Defendant
- 国・裁判所
- 特許番号
- 訴訟タイプ

関係組織・国・訴訟タイプを選択

ケース別の詳細はDarts-IPへアクセス  
※別途Darts-IPのご契約が必要です

Global Litigation

Filters Plaintiff Defendant Country/Territory Type of Case

Customize Columns Export

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PLAINTIFF	DEFENDANT	COUNTRY/TERRITORY	COURT	ACTIVE INGREDIENT	LITIGATED PATENTS	TYPE OF CASE	LAST RECORDED EVENT	DARTS-IP CASE LINK
Libbs Farmacéutica (BR)	Astellas Pharma (US) ***	Brazil	13ª Vara ***	enzalutamide	BR200610359A	Invalidity/Cancellation Action	17-Mar-2025	<a href="#">View Case Details</a>
Astellas Pharma (JP) ***	Ascent Pharmaceuticals (US)	USA	New Jersey District Court	enzalutamide	US2006433829A ***	Infringement Action	02-Jan-2025	<a href="#">View Case Details</a>
Accord Healthcare (GB) ***	Astellas Pharma Europe (GB) ***	United Kingdom	Patents Court	enzalutamide	EP2006748863A	Invalidity/Cancellation Action	07-Nov-2024	<a href="#">View Case Details</a>
Astellas Pharma (JP)	Dr. Reddy's Farmacéutica do Brasil (BR)	Brazil	1ª Câmara Reservada de Direito Empresarial ***	enzalutamide	BR200610359A	Infringement Action	27-Aug-2024	<a href="#">View Case Details</a>
Sandoz (CH) ***	Aragon Pharmaceuticals (US)	EP	EPO BoA 3.3.04 ***	enzalutamide	EP2017187458A	Opposition Action	08-Aug-2024	<a href="#">View Case Details</a>
Astellas Pharma (JP) ***	Qilu Pharma (US) ***	USA	New Jersey District Court	enzalutamide	US2006433829A	Infringement Action	01-Aug-2024	<a href="#">View Case Details</a>
Astellas Pharma (JP) ***	Qilu Pharma (US) ***	USA	New Jersey District Court	enzalutamide	US2006433829A	Infringement Action	01-Aug-2024	<a href="#">View Case Details</a>
Shanghai Fusun Xingtai Pharmaceutical Technology (CN)	The Regents of the University of California ... ***	China	Beijing IP Court ***	enzalutamide	CN200680025545A	Invalidity/Cancellation Action	08-Apr-2024	<a href="#">View Case Details</a>
No data	Kangpu Biopharmaceuticals (CN)	Brazil	INPI - Divisão de Patentes de Farmácia II - CGPA...	enzalutamide	BR11201910559A	Administrative Hearings	11-Dec-2023	<a href="#">View Case Details</a>
Astellas Farma Brasil Importação e Distribuição de Medicame... ***	ACCORD FARMACÉUTICA (BR)	Brazil	1ª Vara Empresarial ***	enzalutamide	BR200610359A	Infringement Action	01-Dec-2023	<a href="#">View Case Details</a>

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# ユーザサポートと開発ロードマップのご案内

# “?”のご活用

## 様々なガイドのご利用

- アップデートのお知らせ
- 使い方ガイド（日本語あり）
- 各種トレーニング資料  
（日本語ページへのリンクあり）
- ユーザコミュニケーションツール  
によるフィードバック

より便利にお使い頂くために

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Search

Tools: Product Selector    Company Selector    Global Pricing Trends

**New Products ?**

March 2025

becondogrel	laroprovstat
becotatug vedotin	mezagitamab
daniluromer	navenibart
daraxonrasib	netanasvir phosphate
dirozalkib	opakalim
doxycitine	relutrigine
doxribtimine	resiquimod sulfate
empasiprubart	sevabertinib
ene...	suraxavir marboxil

**New Drug Approvals EMA**

March 2025

RYTELO	imetelstat sodium	Geron Corporation
WAINZUA	eplontersen	AstraZeneca Pharmaceuticals LP

February 2025

ANDEMBRY	garadacimab	CSL Ltd
HETRONIFLY	serplulimab	Fosun Pharmaceutical Group
KOSTAIVE	zapomeran	Arcturus Therapeutics Inc.

**New Drug Approvals US FDA (NDAs only)**

March 2025

BLUJEPA 750MG	gepotidacin	GSK plc
QFITLIA 20MG/0.2ML, 50MG/0.5ML	fitusiran	Sanofi

February 2025

GOMEKLI	mirdametinib	SpringWorks Therapeutics
ROMVIMZA	vimseltinib	Deciphera Pharmaceuticals LLC

January 2025

**Resources & updates**

- Product updates
- Get started
- Sales demo guided tours
- Training resources
- Contact us
- Feedback & suggestions New

**Training resources**

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- Japanese training resources

各種お知らせや資料へのリンク

日本語サポートページ

# ユーザーサポート



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## カスタマーケア

☎ 0800-170-5577(フリーダイヤル)  
(土日祝日を除く) 9:30~17:30  
✉ [ts.support.jp@clarivate.com](mailto:ts.support.jp@clarivate.com)

専門スタッフが対応。使い方、アクセスなどにお困りの際は、気軽に**日本語**で**問合せ**が可能。

ライフサイエンス&ヘルスケア 製品サポートサイト・Cortellisを初めてお使いになる皆様へ

## Cortellis Product Intelligence

原薬・ジェネリックビジネスのために

## ユーザーサポートサイト

<https://clarivate.com/life-sciences-healthcare/ja/training-support/cortellis/cortellis-product-intelligence/>

利用事例や各種操作ガイドはこちらから

# 2025 Roadmap Highlights

## 拡大されたサプライチェーンデータと洞察を提供

サプライチェーンにおいて、堅固な調達体制の確立、調達コスト効率の向上、流通上の混乱に巻き込まれるリスクを低減する

サプライチェーンを監視し、競争優位性を確保する

世界の輸出入における原薬価格および流通量に関連したインサイトを提供(2025年下半期)

サプライ  
チェーン戦略  
とレジリエンス  
を強化する

市場での地位  
を向上させる

Clarivateの専門家が厳選したデータにより戦略策定を強化

- 特許上の強みと競合他社の戦略について、強化されたインサイトを提供 (2025年下半期)
- 主要なEU市場における承認データの拡大 (2025年下半期)
- 高薬理活性原薬と複雑なジェネリック医薬品に関するデータクラスタリングとドリルダウンによる詳細分析 (2025年下半期)

サプライチェーンの潜在的な弱点を特定し、リスク軽減戦略に反映させる

- サプライチェーンにおける重要な添加剤を特定する(2025年上半期)
- 主要な欧州市場において、ラベルデータの取得から原薬および最終製剤の製造業者、販売業者をマッピングする(2025年上半期/下半期)

市場の主要プレイヤーをマッピングし、ビジネス上の潜在的なギャップと機会を明らかにする

※機能強化について、実装対象となるモジュール(Premium, Global. Sourcing)は未定です。

# Think forward™

## About Clarivate

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