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December 12, 2024

# INTELLECTUAL PROPERTY Information in SANITY

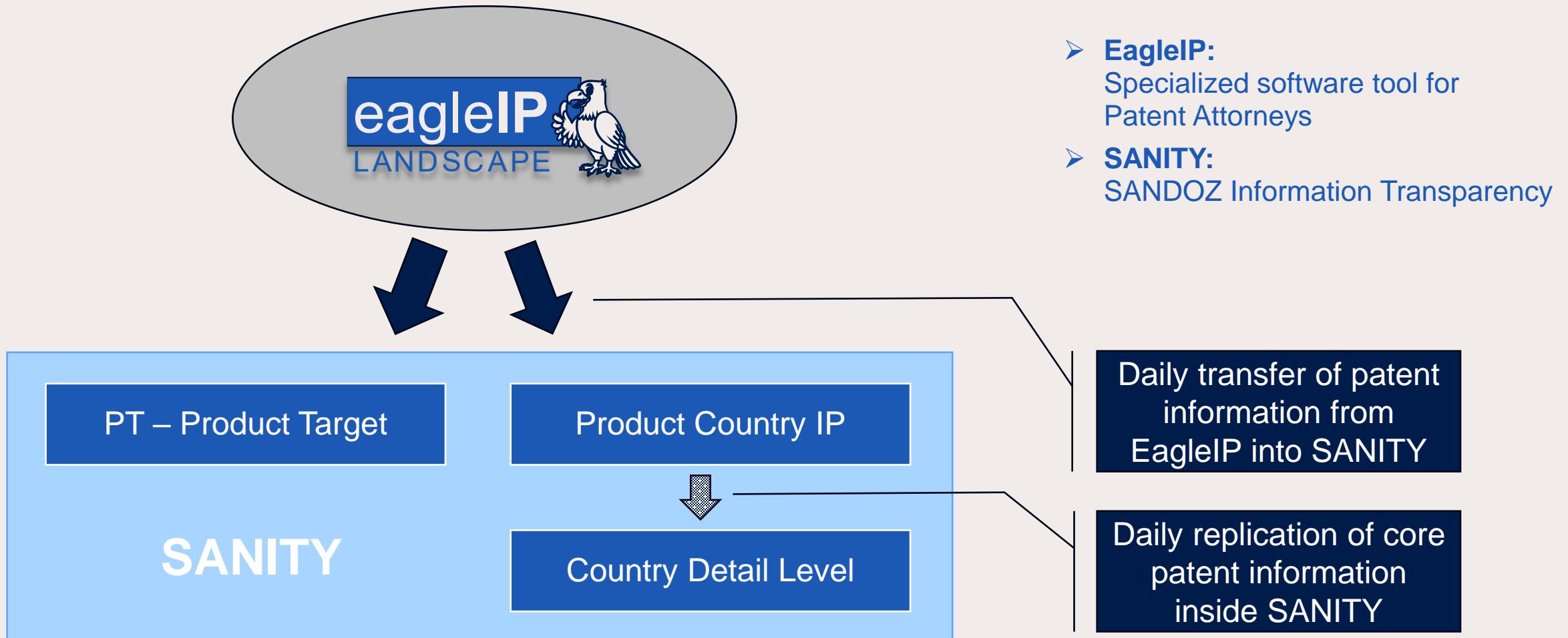
SANDOZ

# IP - Intellectual Property

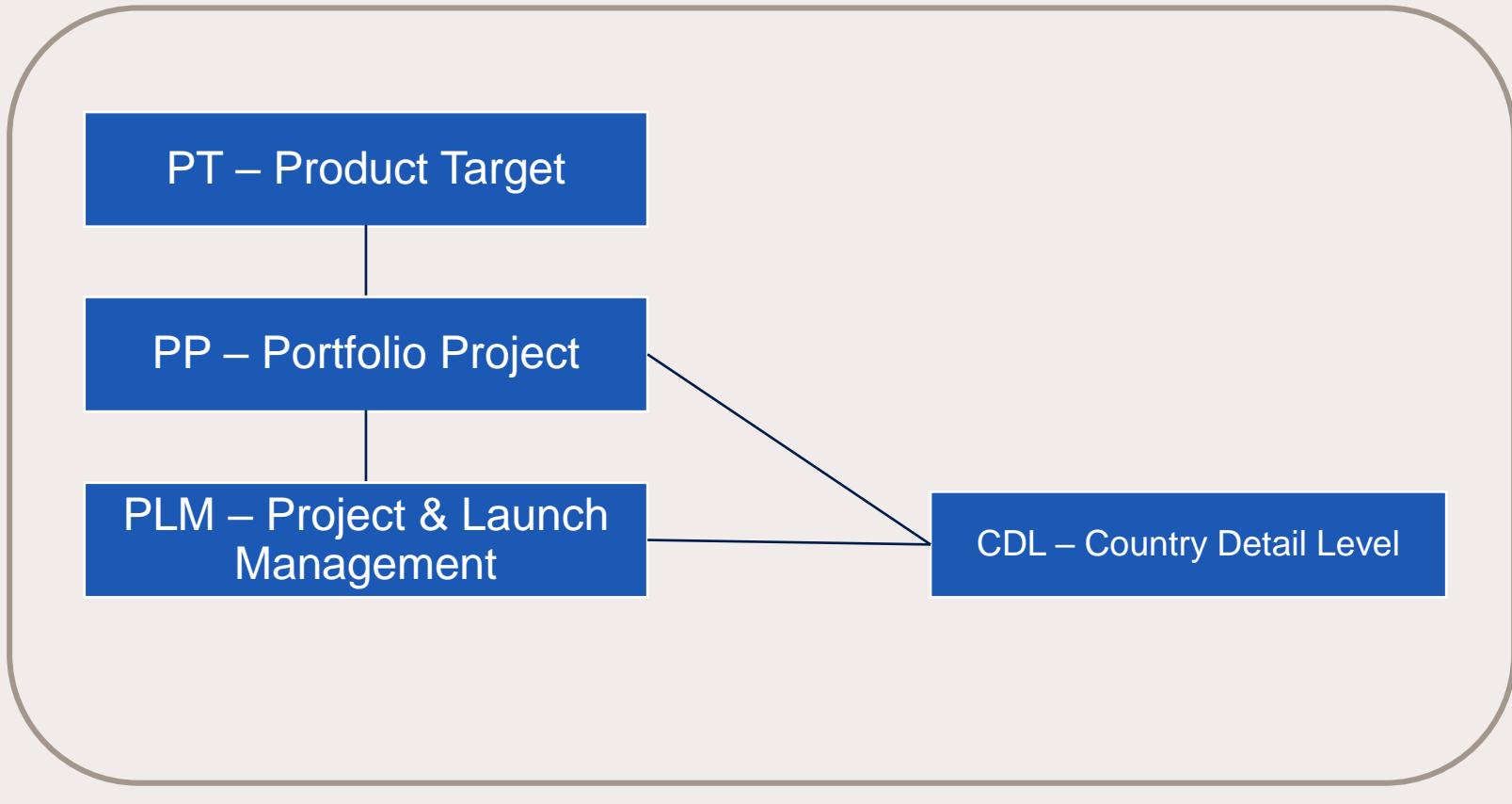
## CONTENT

- 1 IP-related SANITY Structure
- 2 Where to find Intellectual Property data in SANITY

# PATENT INFORMATION: WHERE TO FIND

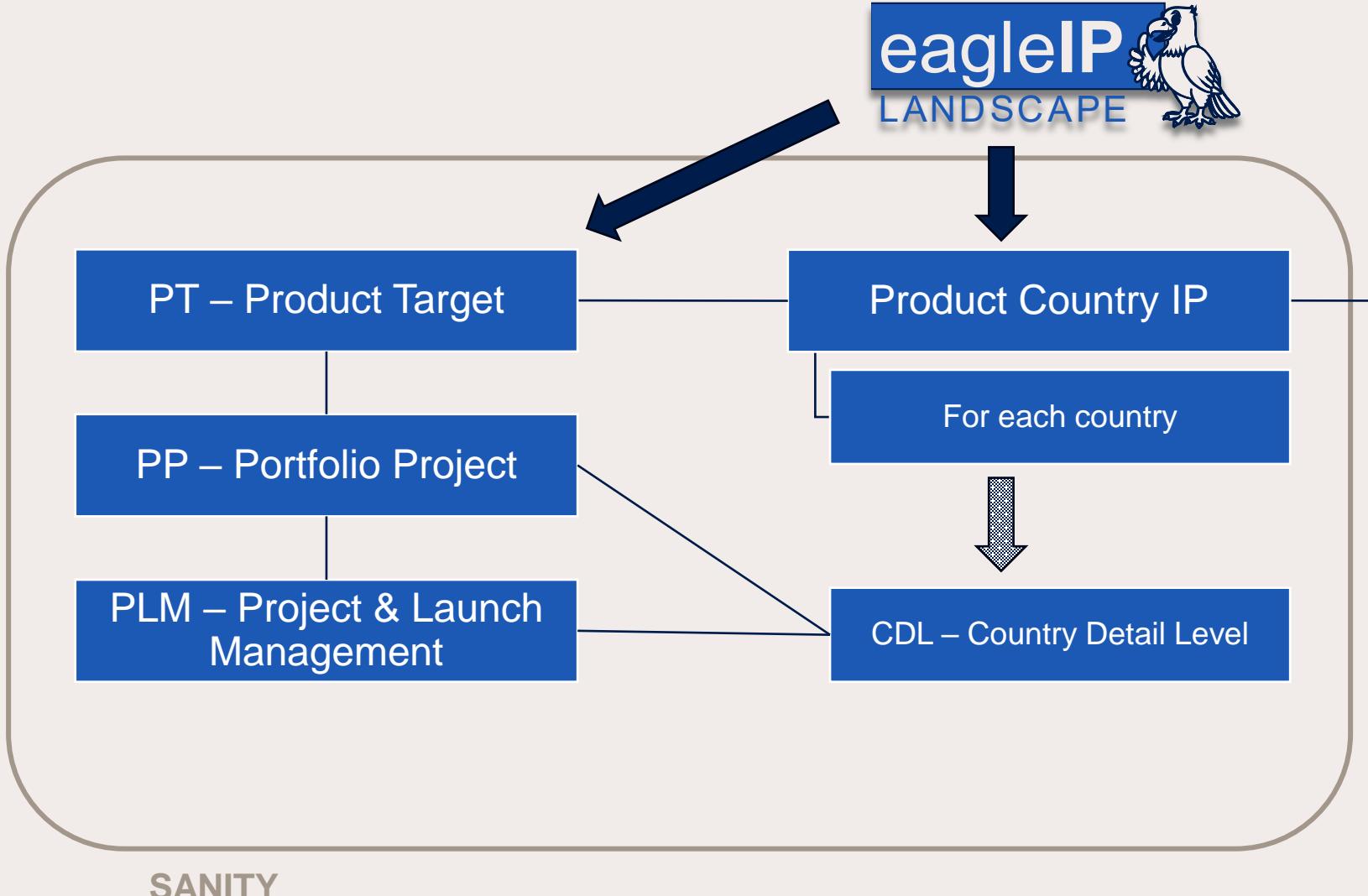


# SANITY CORE STRUCTURE



- **PT - Product Target:**  
The Brand Product. Holds the '*Executive Summary*' from EagleIP.
- **PP - Portfolio Project:**  
Project Order for BD (License) or PD (In-house).
- **PLM - Project & Launch Management:** The work-bench for PMs & LMs (plan, cost, risk, etc.).
- **CDL: Country Detail Level:**  
Detailed information at country level.

# IP DATA REPLICATION



- **EagleIP:**  
Specialized tool for Patent Attorneys
- **Product Country IP:**  
*Our recommendation:*  
*Use these screens for IP information.*
- **PT - Product Target:**  
The Brand Product. Holds the '*Executive Summary*' from EagleIP.
- **PP - Portfolio Project:**  
Project Order for BD (License) or PD (In-house).
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- **CDL: Country Detail Level:**  
Detailed information at country level.

## CONTENT

1 IP-related SANITY Structure

2 Where to find Intellectual Property  
data in SANITY

- On Product Target
- On Country Detail Level

# Executive Summary and IP contact person are available on Product Target



Product Target

The screenshot shows the Product Target interface for Ibuprofen FCT [n/a] (401741) - 3. Step 1 highlights the product title in a red box. Step 2 highlights the 'Details' tab in a red box. Step 3 highlights the 'IP Information' section in a red box.

**Product Target**  
**Ibuprofen FCT [n/a] (401741) - 3**

Originator Company: Boots Therapeutic Area: Other Product Type: Small Molecule Strengths: 400 mg FCT, 800 mg FCT, 600 mg FCT, 200 mg FCT

New Assessment Polymorph Screening Pre-Dev

In order for SAN to product structure to reflect the complex product landscape of SANDOZ, we have moved the dosage form information to the Product strength level. Please reach out to your Port

**Details** Selections & Escalations Patents & Reg Strengths & Sndz Targets Packs & Units Forecasts BD & Scouting Quip

Product Target full Name: Ibuprofen FCT [n/a] (401741) - 3 Originator Product Logo

**IP Information**

Global Patent Attorney: Bostjan Japelj Litigation Attorney: Su Chang Elijha Wong

Latest Executive summary Date: 25.02.2023 03:23

IP Executive Summary: Earliest Gx launch = expiry of launch limiting (LL) compound patent: Dec 2021 AU, EP, JP, RU, UA: 12 Dec 2026 (PTE/SPC)  
TW: 18 Dec 2026 (PTE)  
US: 12 Jan 2026 (PTE) - settled 18 Jan 2027  
No equivalent of compound patent found in MT, IS, SM, CR, CU, DO, EG, GE, IR, JO, KE, OM, QA, TN. Data not locally checked.  
Regulatory exclusivities expire: AU: 7 Nov 2018 (NCE); CA: 1 Nov 2021 (6+2); EU: 27 Sept 2023 (8+2); JP: 16 Jan 2022 (NCE); KR: 28 Jan 2020 (PMS); US: 12 Jul 2017 (NCE-1)

1) Open the Product Target

2) Stay on „Details“

3) Scroll down for „IP Information“

# Country specific dates are available on Product Target

The screenshot shows the Product Target interface for Ibuprofen FCT [n/a] (401741) - 3. A red box highlights the product title. A blue circle with the number 1 points to the top navigation bar. A blue circle with the number 2 points to the 'Patents & Reg' tab, which is highlighted with a red border. A blue circle with the number 3 points to the table below.

Product Target  
Ibuprofen FCT [n/a] (401741) - 3

Originator Company: Boots Therapeutic Area: Other Product Type: Small Molecule

100 mg FCT, 800 mg FCT, 600 mg FCT, 200 mg FCT

New Assessment Polymorph Screening Pre-Dev

In order for SANITY product structure to reflect the complex product

Details Selections & Escalations Patents & Reg Strengths & Sndz Targets Packs & Units Forecasts BD & Scouting Quip

Values shown below are calculated based on information within Patents and Regulatory team managed fields from available sources. Sandoz specific projects may have other dates based on development or strategic decisions.

#	LoE Country	Country...	Eagle IP LoE ...	Expiry of D...	Expiry of ...	Pediatric E...	Patent Expir...	SPC/PTE Expir...	PED Ext. Ex...
1	Austria (Ibuprofen FCT (401741))	AT		12.12.2021			12.12.2021		
2	Australia (Ibuprofen FCT (401741))	AU		12.6.2027			12.12.2021	12.12.2026	12.6.2027
3	Belgium (Ibuprofen FCT (401741))	BE		12.12.2021			12.12.2021		
4	Canada (Ibuprofen FCT (401741))	CA		19.12.2021			19.12.2021		
5	Switzerland (Ibuprofen FCT (401741))	CH		12.6.2027	27.9.2021	27.9.2023	12.12.2021	12.12.2026	12.6.2027
6	Germany (Ibuprofen FCT (401741))	DE		12.12.2026	7.11.2018		12.12.2021	12.12.2026	
7	Denmark (Ibuprofen FCT (401741))	DK		12.12.2021			12.12.2021		
8	France (Ibuprofen FCT (401741))	FR		12.6.2027	27.9.2021	27.9.2023	12.12.2021	12.12.2026	12.6.2027
9	United Kingdom (Ibuprofen FCT (401741))	GB		12.12.2026	27.9.2021	27.9.2023	12.12.2021	12.12.2026	12.6.2027
10	Ireland (Ibuprofen FCT (401741))	IE		12.12.2021			12.12.2021		

View All



Product Target

1) Open the Product Target

2) Select ,Patents & Reg'

## 3) OVERVIEW OF KEY IP DATES:

LoE Country  
Eagle IP LoE Date  
Expiry of Data Exclusivity  
Expiry of Market Exclusivity  
Pediatry Exclusivity  
Patent Expiry Date  
SPC/PTE Expiry Date  
PED Extension Expiry Date

# How to open the Product Country IP

The screenshot shows the Sandoz Product Target interface for Ibuprofen FCT [n/a] (401741) - 3. Step 1 highlights the product target header. Step 2 highlights the 'Patents & Reg' tab. Step 3 highlights the 'Austria (Ibuprofen FCT (401741)) AT' row in the table, which is then expanded into a detailed view.

Product Target  
Ibuprofen FCT [n/a] (401741) - 3

1

2

3

Values shown below are calculated based on information within Patents and Regulatory team managed fields from available sources. Sandoz specific projects may have other dates based on development or strategic decisions.

	LoE Country	Country...	Eagle IP LoE ...	Expiry of D...	Expiry of ...	Pediatric E...	Patent Expir...	SPC/PTE Expir...	PED Ext. Ex...
1	<input type="checkbox"/> Austria (Ibuprofen FCT (401741))	AT		12.12.2021			12.12.2021		
2	<input type="checkbox"/> Australia (Ibuprofen FCT (401741))	AU		12.6.2027					
3	<input type="checkbox"/> Belgium (Ibuprofen FCT (401741))	BE		12.12.2021					
4	<input type="checkbox"/> Canada (Ibuprofen FCT (401741))								
5	<input type="checkbox"/> Switzerland (Ibuprofen FCT (401741))	CH	12.6.2027	27.9.2021					
6	<input type="checkbox"/> Germany (Ibuprofen FCT (401741))	DE	12.12.2026	7.11.2018					
7	<input type="checkbox"/> Denmark (Ibuprofen FCT (401741))	DK	12.12.2021						
8	<input type="checkbox"/> France (Ibuprofen FCT (401741))	FR	12.6.2027	27.9.2021					
9	<input type="checkbox"/> United Kingdom (Ibuprofen FCT (401741))	GB	12.12.2026	27.9.2021					
10	<input type="checkbox"/> Ireland (Ibuprofen FCT (401741))	IE	12.12.2021						

Product Country IP (10+)  
10+ items • Sorted by Country Iso Code • Updated a few seconds ago

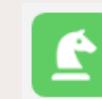
Details Selections & Escalations **Patents & Reg** Strengths & Sndz Targets Packs & Units Forecasts BD & Scouting Quip

Product Target  
Austria: Afatinib dimaleate FCT [Gilotrif (US), Giotr] (400014)

Eagle IP LoE Date  
12.06.2027

Details 3D Slide Projects Field History Tracking

Product Target Afatinib dimaleate FCT (400014)



## Product Country IP

1) Open the Product Target

2) Select ,Patents & Reg'

3) Open the blue hyperlink

**Country Default LoE Dates**  
contains all country specific IP data from EagleIP and the 'Executive Summary'.

# Product Country IP DETAILS

Product Country IP  
**Austria: Ibuprofen FCT [n/a] (401741) - 3**

Eagle IP LoE Date  
12.06.2027

**1**

*Confidential and Privileged*

**Details** 3D Slide Projects Field History Tracking

Product Target	Afatinib dimaleate FCT (400014)	Country ⓘ	Austria
Eagle IP LoE Date ⓘ	12.06.2027	Country Region ⓘ	Europe
		Override Eagle IP LoE Date ⓘ	<input type="checkbox"/>
		Market Formation Date ⓘ	12.06.2027
		Risk Level	

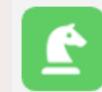
**Regulatory**

Date of First Marketing Authorization ⓘ	27.09.2013	No Data Protection ⓘ	<input type="checkbox"/>
Expiry of Data Exclusivity ⓘ	27.09.2021		
Expiry of Market Exclusivity ⓘ	27.09.2023	Pediatric Status ⓘ	
Pediatric Exclusivity ⓘ			

**Patents**

Launch Limiting Patent ⓘ	EP1345910	Family Alias ⓘ	Specific compound for afatinib (B1)
Patent Expiry Date	12.12.2021	Legal Status ⓘ	Granted
SPC/PTE Expiry Date	12.12.2026	SPC Status ⓘ	Granted
PED Ext. Expiry Date	12.06.2027	3D Best Case Launch date	
		PED Status ⓘ	Granted
		LoE Status ⓘ	LOE in the future

**3D Case - Best Case**



# Product Country IP

## 1) Stay on Details

The Eagle IP LoE Date is copied into the 'Market Formation Date', which might be overridden by Portfolio earliest launch assumptions (mainly used for Canada).

## Regulatory Information

Includes expiry dates for data and market exclusivity, as far as available.

## Patent Information

Includes information on launch limiting patent (mostly compound patent) including patent number, legal status, expiry date and additional extensions.

# Product Country IP DETAILS

1) Stay on Details and scroll down

Patent Assessments with 3D Evaluation Including POS (Probability Of Success)

Klick to expand or collapse the section

Country specific LoE Comments



Product Country IP

Product Country IP  
Austria: Ibuprofen FCT [n/a] (401741) - 3

Eagle IP LoE Date  
12.06.2027

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1

Details 3D Slide Projects Field History Tracking

3D Case - Best Case

3D Best Case Manufacturing Country	BG
3D Best Case Manufacturing Risk	Green
3D Best Case Trigger	Before PTE Expiry
3D Best Case Requires	Compound patent + PTE to be invalidated Juno had started an invalidity proceeding against the compound patent. the parties have settled prior to hearing Infringement proceedings on MOTs stayed. BMS settled for a Juno launch in Feb 2023
3D Best Case POS	0%

3D Case - Most Likely

3D Case - Lowest Risk

LoE Strategy Comment

LoE Strategy Comment ⓘ Polymorph, formulation and second indication patents represent medium-low risk. They are deemed invalid; second indication patent revoked at the EPO, polymorph patent opposed. Formulation patent still pending. Carved out of the second indication patents may be possible. L @ R may need to be considered.

# Product Country IP DETAILS



# Product Country IP

1 Product Country IP Austria: Ibuprofen FCT [n/a] (401741) - 3

Details **3D Slide** Projects Field History Tracking

IP LOE 1 ▾ Data updated: Today at 09:56

Title: Ibuprofen FCT (401741)			
	Best Case	Most Likely	Lowest Risk
Manufacturing Country	BG	BG	BG
Manufacturing Risk	●	●	●
Launch Date	Q2/2022	02-Jan-2023	16-May-2023
Launch Triggering Event	Before PTE Expiry	Settlement negotiations	MM MOT expiry
Requires	Compound patent + PTE to be invalidated Juno had started an invalidity proceeding against the compound patent. the parties have settled prior to hearing Infringement proceedings on MOTs stayed. BMS settled for a Juno launch in Feb 2023	BMS and Juno settled for an early launch in Feb 2023 BMS is offering the same terms to us Launch full label 4 month before expiry of MM and MDS MOT patent expiry.	MM patents expired MDS patent expired with carve-out of MCL only
POS	0%	60%	100%

1) Select 3D Slide

3D Slides

provide an easy to read overview on 3 different launch scenarios

for selected products and scopes

# Product Country IP Executive Summary & IP Contact Person

Product Country IP  
**Austria: Ibuprofen FCT [n/a] (401741) - 3**

Eagle IP LoE Date

*Confidential and Privileged*

**Details** 3D Slide Projects More ▾

Product Target: Ibuprofen FCT (401741) | Country: Austria | Eagle IP LoE Date: 12 Dec 2026 (PTE/SPC)

Country Region: Europe | Override Eagle IP LoE Date: No | Market Formation Date: 12 Dec 2026 (PTE/SPC)

Risk Level: No Data Protection

**Regulatory**

Date of First Marketing Authorization: No Data Protection

**External Links to Eagle IP**

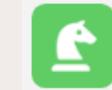
- EagleIP Dashboard Link
- Bubble Chart Link

**Related Target Information**

Global Patent Attorney: Bostjan Japelj  
Litigation Attorney: Su Chang Elijah Wong

IP Executive Summary: Earliest Gx launch = expiry of launch limiting (LL) compound patent: Dec 2021  
AU, EP, JP, RU, UA: 12 Dec 2026 (PTE/SPC)  
TW: 18 Dec 2026 (PTE)  
US: 12 Jan 2026 (PTE) - settled 18 Jan 2027  
No equivalent of compound patent found in MT, IS, SM, CR, CU, DO, EG, GE, IR, JO, KE, OM, QA, TN. Data not locally checked.

Regulatory exclusivities expire: AU: 7 Nov 2018 (NCE); CA: 1 Nov 2021 (6+2); EU: 27 Sept 2023 (8+2); JP: 16 Jan 2022 (NCE); KR: 28 Jan 2020 (PMS); US: 12 Jul 2017 (NCE-1)



Product Country IP

Available on all  
,Country Default LoE  
Dates' pages

IP Contact Persons

Executive Summary

## CONTENT

1 IP-related SANITY Structure

2 Where to find Intellectual Property  
data in SANITY

- On Product Target
- On Country Detail Level

# COUNTRY DETAIL LEVELS are available on Projects

Portfolio Project  
**Ibuprofen FCT (302252)**

+ Follow Edit Create Project Selling Units Create BD Deal Create Project & Launch Mgmt Discontinue Portfolio Project

Project Status Finished	Product Class Gx	Therapeutic Area Other	Product Target <a href="#">Ibuprofen FCT (401741)</a>	Originator Product Name n/a	Selected Product Target <a href="#">Ibuprofen FCT (401741)</a>
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Discontinued → Under consideration → On Hold → Active

Details BD & PLM Str & Packs **Country Detail** NPV & Fcsts Selections & Escalations Regulatory Quip

**Portfolio Project**

Select  
'Country Detail'  
on Portfolio Project

Project & Launch Management  
**Ibuprofen FCT (302252) SDC DEHO**

+ Follow Request Forecast Update Cancel Forecast Requests Edit Create MC Proj

Details Project Timeline Budget Overview Team & Risks Supply Chain **Countries & Fcsts** Study & Reg News & Escalations More ▾

**Key Countries (PD) (2)**  
2 items • Sorted by Country • Filtered by Key Project Country, Country Project Status, Interest Stage • Updated a few seconds ago

CDL Full Name	Country	Risk, Status, & Interest	Country La...	Forecast S...	Finance Target ...	Current pl...	Current pl...	Market For...	iPM
Ibuprofen FCT (302...	United Kingdom	Active				USD 0,00			
Ibuprofen FCT (302...	Germany	Launched     Forecasted Int...				USD 0,00			

[View All](#)

**Project & Launch Management**

Select  
'Countries & Fcsts'  
on Project & Launch Management

**Countries Detail Level (10+)**  
10+ items • Sorted by CDL Full Name • Updated a few seconds ago

CDL Full Name ↑	Country	Parent Reg... ↓	Risk, Status, & Interest	Country La... ↓	Forecast Fi... ↓
Ibuprofen FCT (302252) AM	Armenia	Europe	Active		
Ibuprofen FCT (302252) AT	Austria	Europe			
Ibuprofen FCT (302252) BA	Bosnia and Herzegovina	Europe	Approved		

# PATENT INFORMATION ON COUNTRY DETAIL LEVEL



Country Detail Level

Country Detail Level  
**Ibuprofen FCT (302252) GB**

+ Follow Manage Pipeline Change Owner Manage Date Fields E

**Details** Launch Timeline Forecasts & Tgt Mtgs & Escalations Regulatory Status & SPC Team & Sites More ▾

> All details

▼ Summary

▼ IP Information

Eagle IP LOE date LoE Status Expired

Product Country IP Link [LoE-0101581](#)

Market Formation Date ⓘ

> Project & Launch Management

▼ Regulatory dates

Regulatory Filing Status ⓘ Pre-filing (Pre/Post)

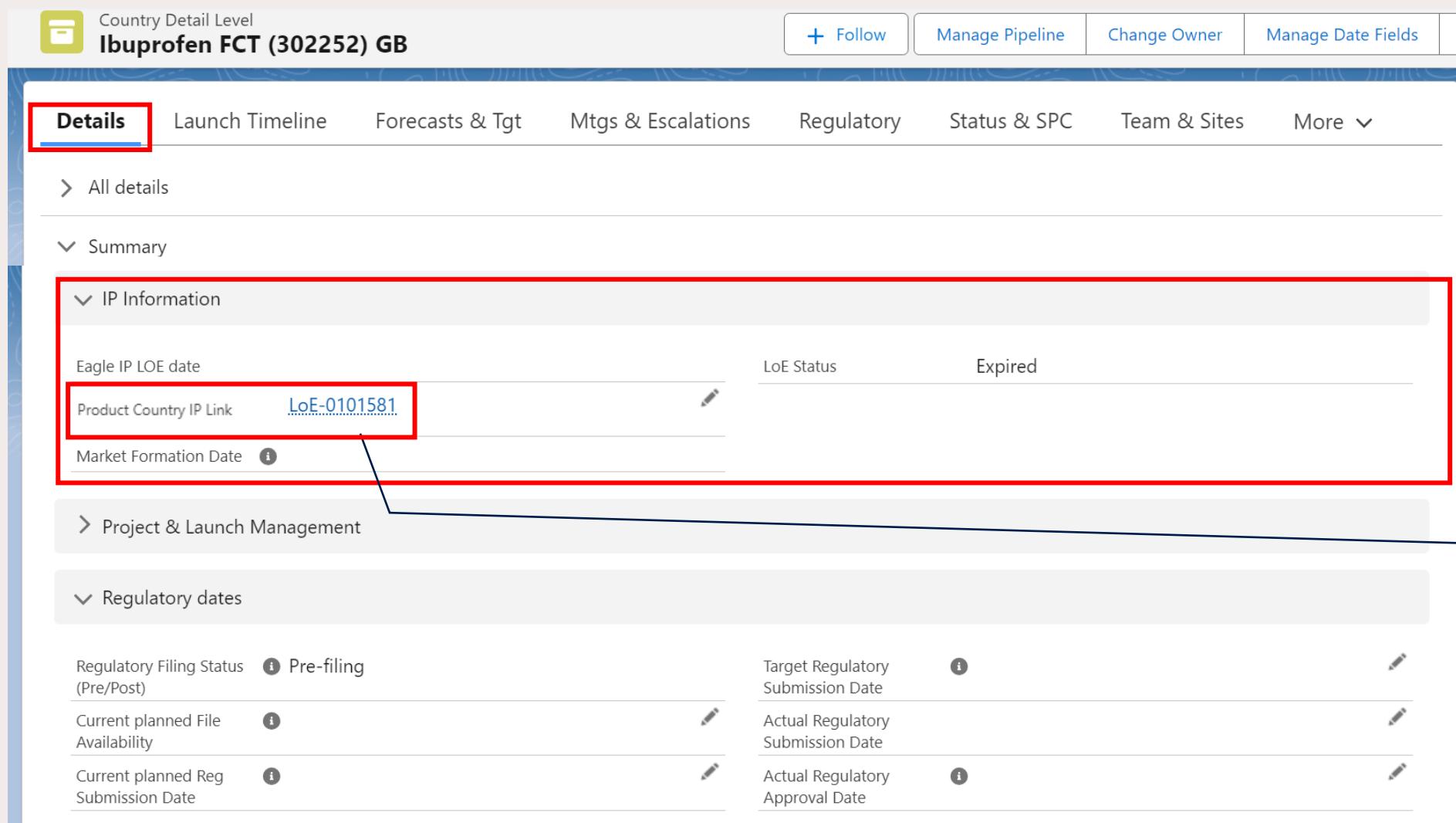
Current planned File Availability ⓘ

Current planned Reg Submission Date ⓘ

Target Regulatory Submission Date ⓘ

Actual Regulatory Submission Date ⓘ

Actual Regulatory Approval Date ⓘ



Scroll Down in 'Details' to find the Patent Information

**SPECIAL**

**RECOMMENDATION**  
Open the link to see all IP information in 'Country Default LoE Dates'

# LAUNCH TIMELINES versus PATENT INFORMATION



Country Detail Level

Country Detail Level  
**Ibuprofen FCT (302252) GB**

+ Follow Manage Pipeline Change Owner Manage Date Fields E

Details **Launch Timeline** Forecasts & Tgt Mtgs & Escalations Regulatory Status & SPC Team & Sites More ▾

▼ Current timeline

Launch Plan vs Target Light	● Red
Launch Plan vs LoE Light	● Green
Current planned File Availability	● 01.10.2019
Current planned Reg Submission Date	● 04.11.2019
Data Exclusivity Expiry Date	● 01.11.2019
Current expected Reg. Approval date	● 04.03.2021

Common procedure end date (Est.) ● 08.11.2019

National approval date (Est.) ● 01.01.2021

Reimbursement date (Est.) ● 02.03.2021

Manufacturer supply readiness (Est.) ● 30.07.2021

Internal supply readiness date (Est.) ● 29.08.2021

Current planned Launch Date ● 14.10.2024

**Data Exclusivity Expiry Date**

**Traffic Light: Planned Launch versus LoE**

Select  
'Launch Timeline'

S A N D O Z