

Bettina Meister
Bernhard Hauth
December 12, 2024

INTELLECTUAL PROPERTY Information in SANITY

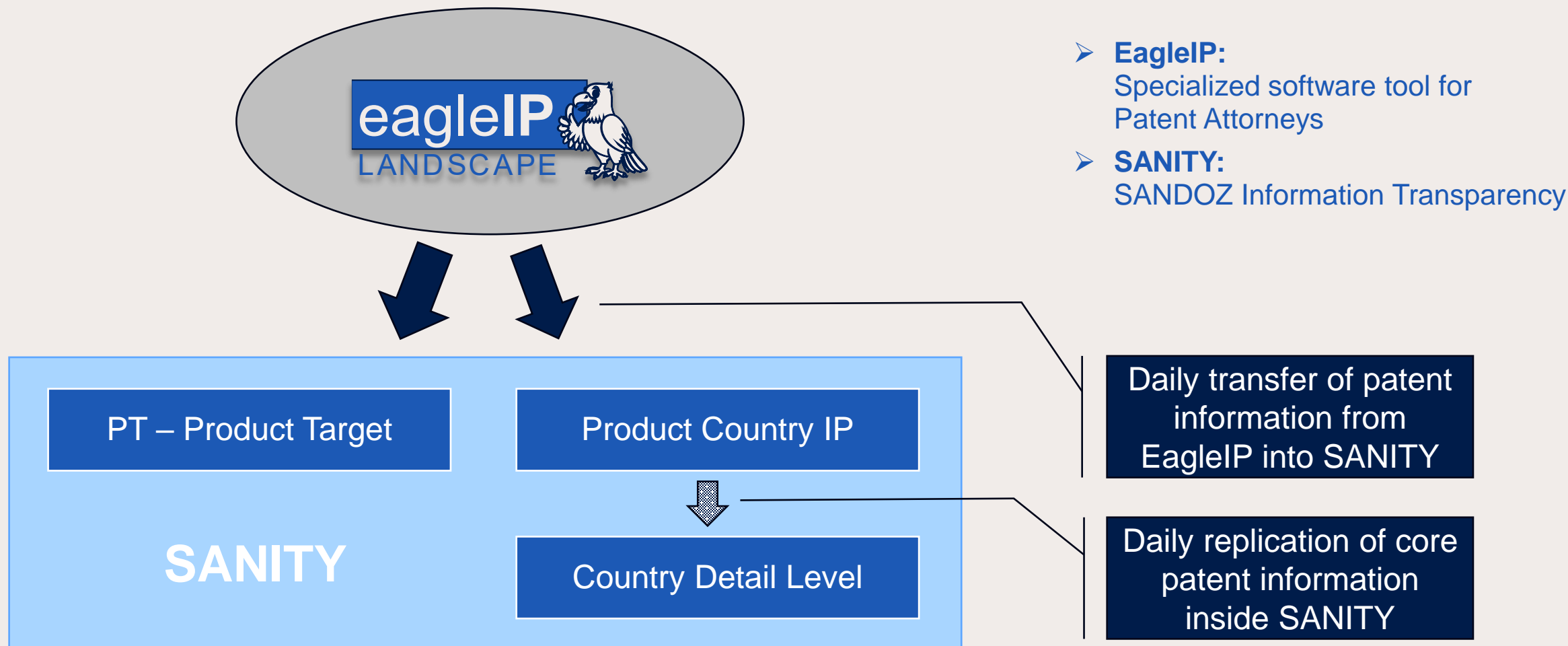
SANDOZ

CONTENT

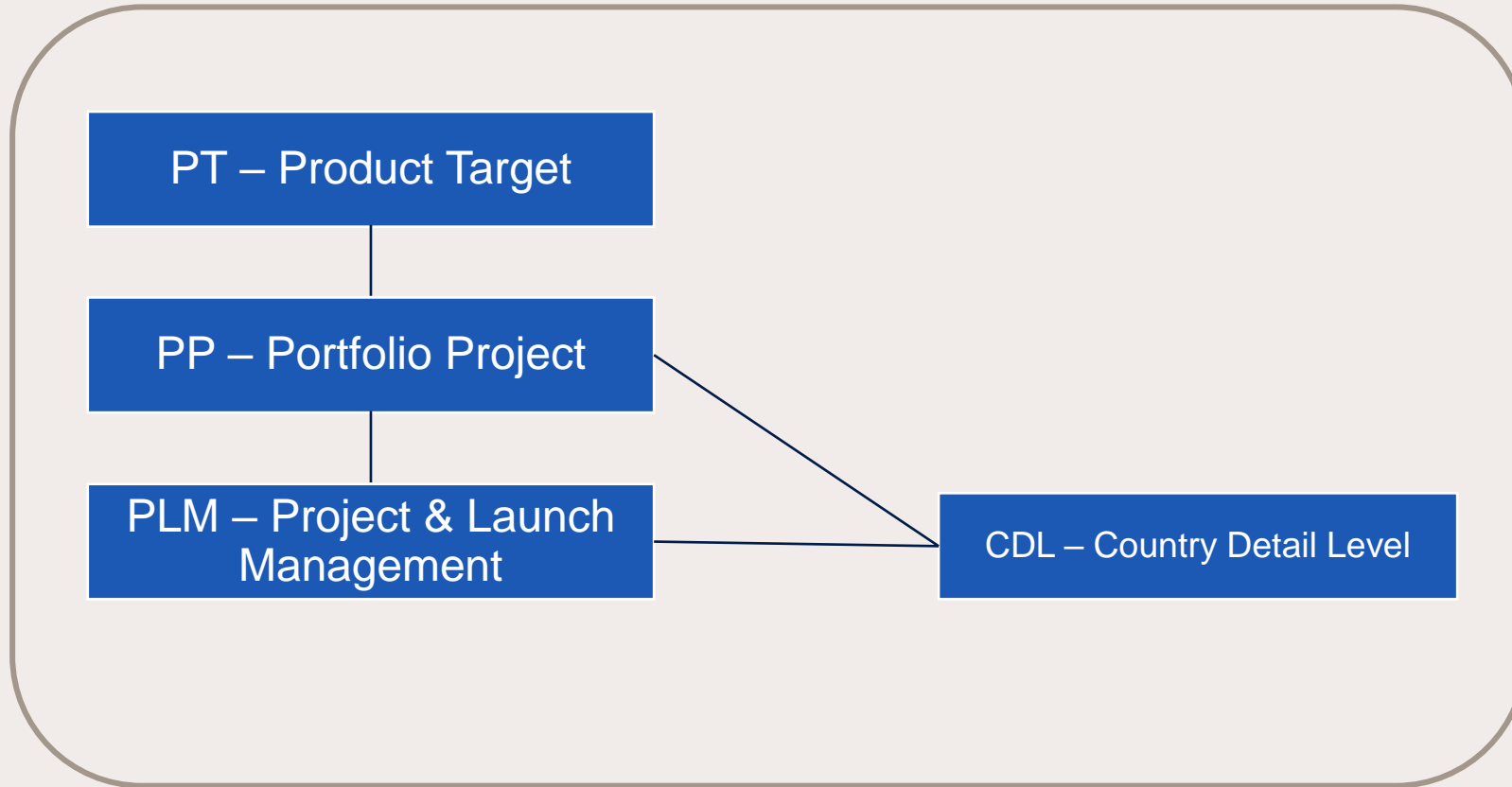
1 IP-related SANITY Structure

2 Where to find Intellectual Property data in SANITY

PATENT INFORMATION: WHERE TO FIND



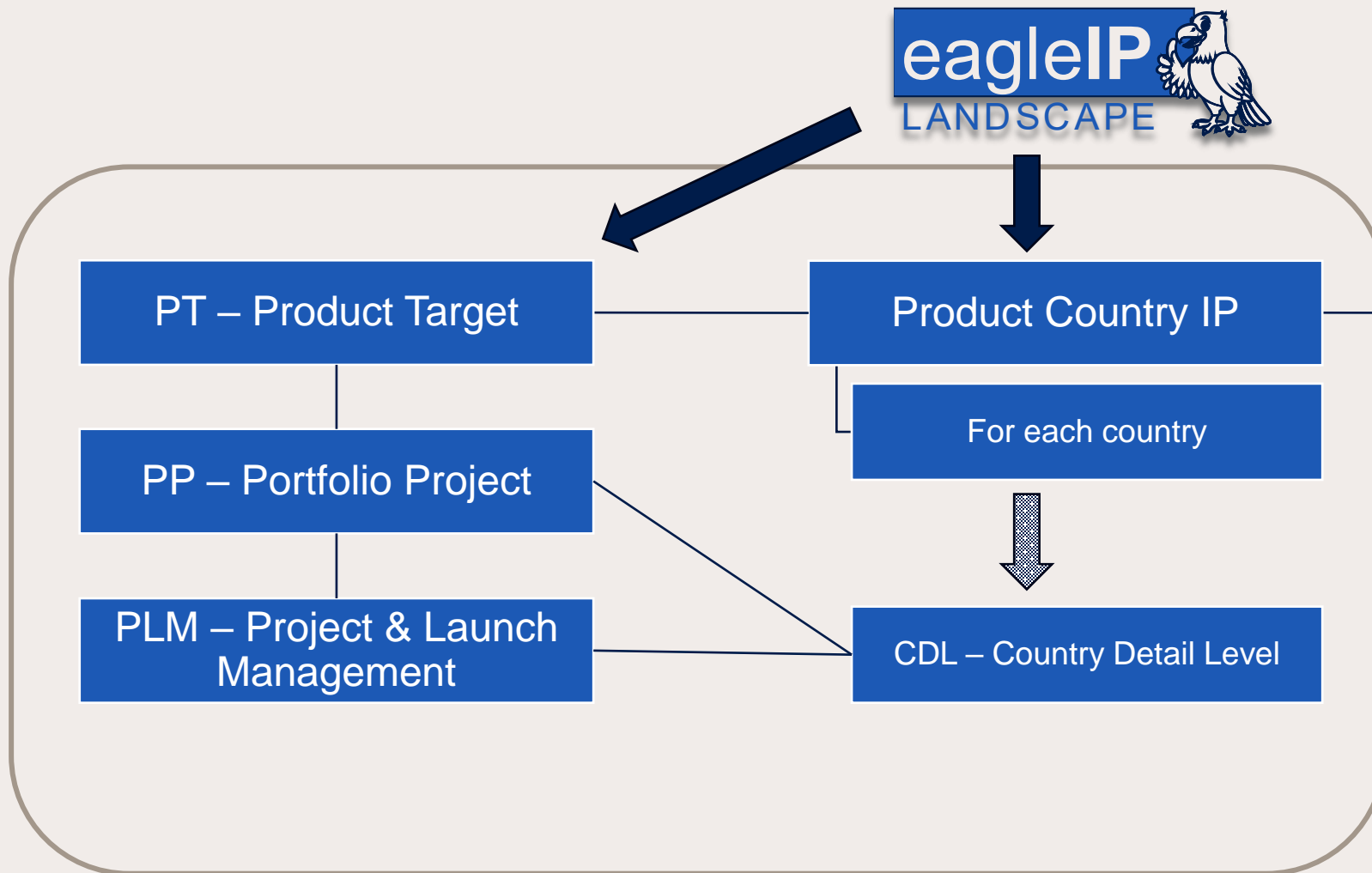
SANITY CORE STRUCTURE



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



SANITY

- **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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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

1

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

+ Follow Edit Manage Target APIs Manage Strength / Dosage Manage Packs and Units New Sandoz Product

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 SANDOZ 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

2

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

3

IP Information

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

Product Target

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

Originator Company

Boots

Therapeutic Area

Other

Product Type

Small Molecule

Strengths

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

+ Follow

Edit

Manage Target APIs

Manage Strength / Dosage

Manage Packs and Units

New Sandoz

New

Assessment

Polymorph Screening

Pre-Dev

In order for SANITY product structure to reflect the complex product structure of SANDOZ, we have moved the dosage form information to the Product strength level. Please reach out to your Portfolio Operations Team for more information.

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.

Product Country IP (10+)

10+ items • Sorted by Country Iso Code • Updated a few seconds ago

	<input type="checkbox"/> LoE Country	Country...	Eagle IP LoE ...	Expiry of D...	Expiry of ...	Pediatric E...	Patent Expir...	SPC/PTE Exp...	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			12.12.2021	12.12.2026	12.6.2027	
3	<input type="checkbox"/>	Belgium (Ibuprofen FCT (401741))	BE	12.12.2021			12.12.2021			
4	<input type="checkbox"/>	Canada (Ibuprofen FCT (401741))	CA	19.12.2021			19.12.2021			
5	<input type="checkbox"/>	Switzerland (Ibuprofen FCT (401741))	CH	12.6.2027	27.9.2021	27.9.2023	12.12.2021	12.12.2026	12.6.2027	
6	<input type="checkbox"/>	Germany (Ibuprofen FCT (401741))	DE	12.12.2026	7.11.2018		12.12.2021	12.12.2026		
7	<input type="checkbox"/>	Denmark (Ibuprofen FCT (401741))	DK	12.12.2021			12.12.2021			
8	<input type="checkbox"/>	France (Ibuprofen FCT (401741))	FR	12.6.2027	27.9.2021	27.9.2023	12.12.2021	12.12.2026	12.6.2027	
9	<input type="checkbox"/>	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	<input type="checkbox"/>	Ireland (Ibuprofen FCT (401741))	IE	12.12.2021			12.12.2021			

View All



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
- Pediatric Exclusivity
- Patent Expiry Date
- SPC/PTE Expiry Date
- PED Extension Expiry Date

How to open the Product Country IP



Product Country IP

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

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

Assessment

In order for SANITY product structure to reflect the complex product structure of SANDOZ, we have moved the dosage form information to the Product strength level. Please reach out to your Portfolio Operations Team for more information.

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.

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10+ items • Sorted by Country Iso Code • Updated a few seconds ago

	<input type="checkbox"/> LoE Country	Country...	Eagle IP LoE ...	Expiry of D...	Expiry of ...	Pediatric E...	Patent Expir...	SPC/PTE Exp...	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 (4017...))	AU	12.6.2027					
3	<input type="checkbox"/>	Belgium (Ibuprofen FCT (40174...))	BE	12.12.2021					
4	<input type="checkbox"/>	Canada (Ibuprofen FCT (401741))	CA						
5	<input type="checkbox"/>	Switzerland (Ibuprofen FCT (40...))	CH	12.6.2027	27.9.2021				
6	<input type="checkbox"/>	Germany (Ibuprofen FCT (4017...))	DE	12.12.2026	7.11.2018				
7	<input type="checkbox"/>	Denmark (Ibuprofen FCT (4017...))	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 FC...)	GB	12.12.2026	27.9.2021				
10	<input type="checkbox"/>	Ireland (Ibuprofen FCT (401741))	IE	12.12.2021					

Product Country IP
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 \(400014\)](#)

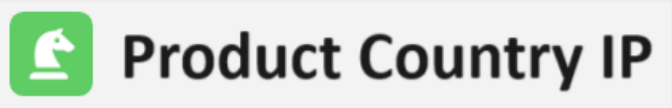
1) Open the Product Target

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)

Eagle IP LoE Date ⓘ

12.06.2027

Country ⓘ

Austria

Country Region ⓘ

Europe

Override Eagle IP LoE Date ⓘ

☐

Market Formation Date ⓘ

12.06.2027

Risk Level

Regulatory

Date of First Marketing Authorization ⓘ

27.09.2013

Expiry of Data Exclusivity ⓘ

27.09.2021

Expiry of Market Exclusivity ⓘ

27.09.2023

Pediatric Exclusivity ⓘ

No Data Protection ⓘ

☐

Pediatric Status ⓘ

Patents

Launch Limiting Patent ⓘ

EP1345910

Patent Expiry Date

12.12.2021

SPC/PTE Expiry Date

12.12.2026

PED Ext. Expiry Date

12.06.2027

Family Alias ⓘ

Specific compound for afatinib (BI)

Legal Status ⓘ

Granted

SPC Status ⓘ

Granted

3D Best Case Launch date

PED Status ⓘ

Granted

LoE Status ⓘ

LOE in the future

3D Case - Best Case

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




Product Country IP

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






Eagle IP LoE Date
12.06.2027

1

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Details3D SlideProjectsField 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

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	<div></div>	<div></div>	<div></div>
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

+ Follow Clone Edit Delete

Eagle IP LoE Date

Confidential and Privileged

Details 3D Slide Projects More

Product Target
[Ibuprofen FCT \(401741\)](#)

Eagle IP LoE Date

Country **Austria**

Country Region **Europe**

Override Eagle IP LoE Date

Market Formation Date

Risk Level

Regulatory

Date of First Marketing Authorization

No Data Protection

External Links to Eagle IP

EagleIP Dashboard Link
[EagleIP Dashboard Link](#)

Bubble Chart Link
[Bubble Chart Link](#)

Related Target Information

Global Patent Attorney
Bostjan Japelj

Litigation Attorney
Su Chang Elijha 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)

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

Product Class

Therapeutic Area

Product Target

Originator Product Name

Selected Product Target

Finished

Gx

Other

[Ibuprofen FCT \(401741\)](#)

n/a

[Ibuprofen FCT \(401741\)](#)

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 Proje

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
1	Ibuprofen FCT (302...	United Kingdom	Active			USD 0,00				
2	Ibuprofen FCT (302...	Germany	Launched Forecasted Int...			USD 0,00				

View All

Countries Detail Level (10+)

10+ items • Sorted by CDL Full Name • Updated a few seconds ago

Change Owner

Manage CDLs (PM)

	CDL Full Name	Country	Parent Reg...	Risk, Status, & Interest	Country La...	Forecast Fi...
1	<input type="checkbox"/> Ibuprofen FCT (302252) AM	Armenia	Europe	Active		
2	<input type="checkbox"/> Ibuprofen FCT (302252) AT	Austria	Europe			
3	<input type="checkbox"/> Ibuprofen FCT (302252) BA	Bosnia and Herzegovina	Europe	Approved		


Project & Launch Management

Select
,Countries & Fcsts'
on Project & Launch Management

15

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PATENT INFORMATION ON 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

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‘

16 Business Use Only

SANDOZ

LAUNCH TIMELINES versus PATENT INFORMATION

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

●

Launch Plan vs LoE Light

●

Current planned File Availability

i

01.10.2019

Current planned Reg Submission Date

i

04.11.2019

Data Exclusivity Expiry Date

i

01.11.2019

Current expected Reg. Approval date

i

04.03.2021

Common procedure end date (Est.)

i

08.11.2019

National approval date (Est.)

i

01.01.2021

Reimbursement date (Est.)

i

02.03.2021

Manufacturer supply readiness (Est.)

i

30.07.2021

Internal supply readiness date (Est.)

i

29.08.2021

Current planned Launch Date

i

14.10.2024

Select
,Launch Timeline‘

Data Exclusivity
Expiry Date

Traffic Light: Planned
Launch versus LoE

SANDOZ