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December 12, 2024



Understanding IP data in Sanity (IP basics)

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IP - Intellectual Property

CONTENT

Part 1: Understanding IP data in Sanity

- Regulatory protection
- Patent protection
- Loss of exclusivity
- 3D concept

Part 2: Demo of IP data in Sanity (B. Hauth)

Part 3: Q&A

Why do we need IP data in SANITY?

SANITY:
application for
portfolio & pipeline
transparency

- Branded products are protected by **Intellectual property rights** impacting our pipeline
- IP department provides information on loss of exclusivity (LOE) for better pipeline planning



What is a regulatory exclusivity?

Research



- Research for discovery of new molecules

Product development



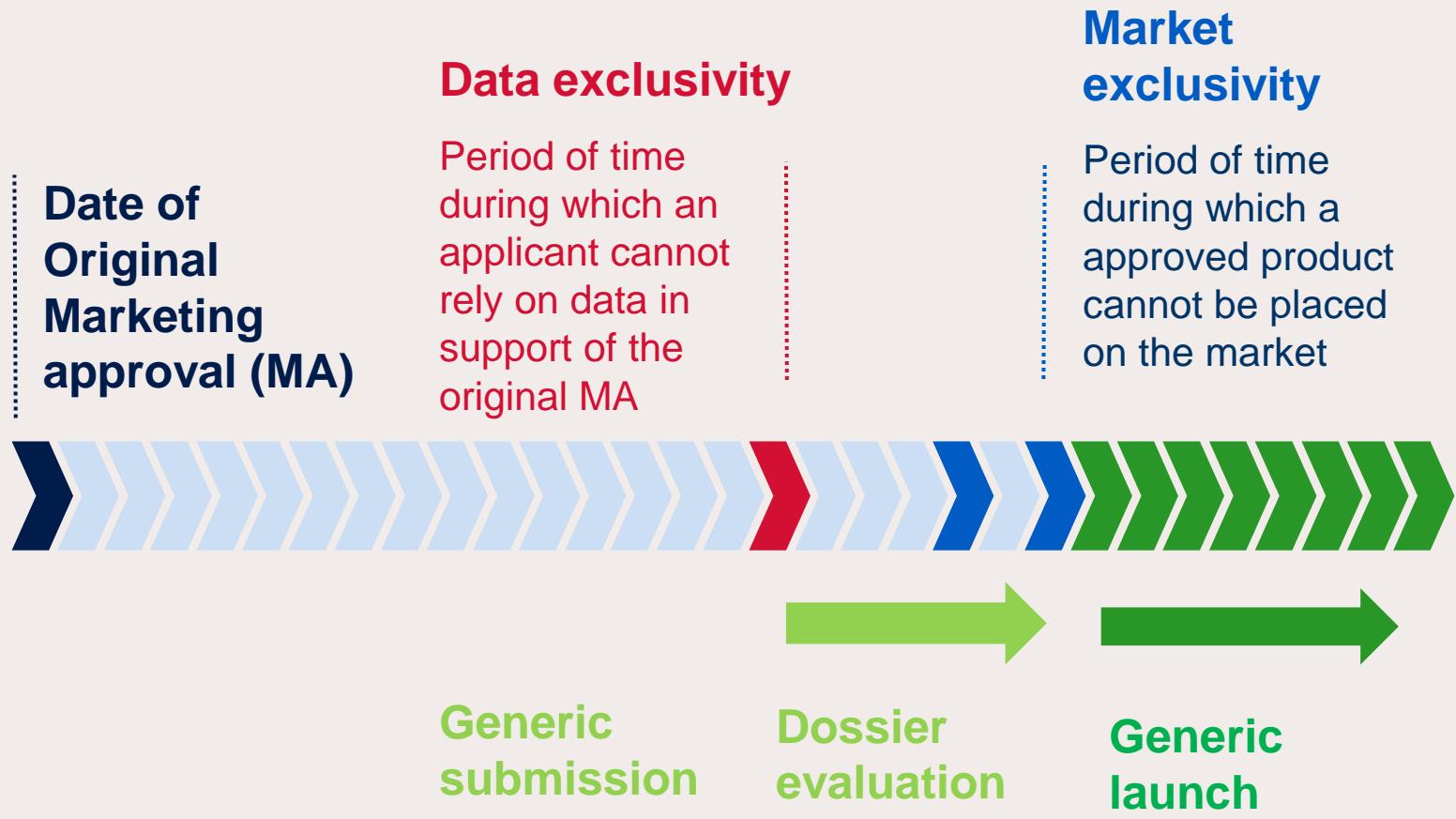
- Clinical studies to show that a medicine is safe and efficacious
- Regulatory approval

Medicine available for patients



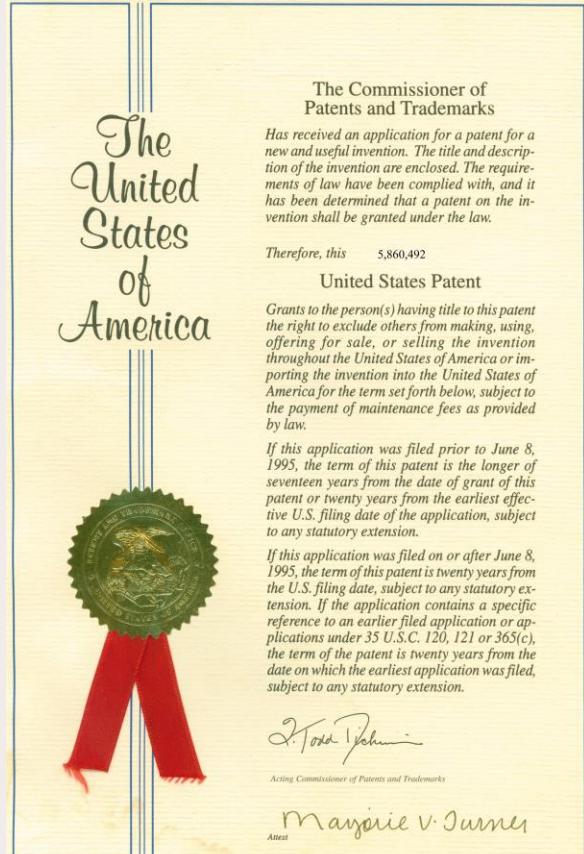
- New medicinal products enter the market after extensive, time-consuming and cost-intensive research, studies and regulatory procedures

Regulatory exclusivities vary per country



Country	Data exclusivity	Market exclusivity
Australia	5 years	-
Canada	6 years	2 years
China	up to 6 years	-
EU	8 years	2 years (+1 year)
Japan	8 years	-
Russia	4 years	2 years
South Korea	6 years	-
Taiwan	3 years	2 years
Turkey	6 years	-
Ukraine	5 years	-
USA	5 years	-

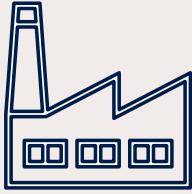
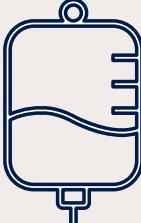
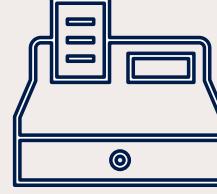
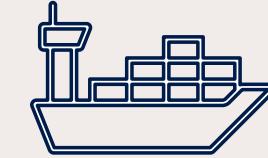
Patent protection



- Protect technical inventions
- Granted by a Patent Office on a country-by-country basis
- Provide a monopoly for around 20 years (depending on national law) to the inventor

Originator patents can define our pre-launch activities and launch timing

A patent gives a patentee the exclusive right to:

Make	Use	Sell	Offer to Sell	Import
				

the invention defined by the claims of the patent, and to stop others from doing so.

Patent protection in the pharmaceutical field



Launch limiting (LL) patents

- no invalidity position available
- no work around possible
- prevent launch



Launch relevant (LR) patents

- not prevent launch / manufacture, but...
- may result in injunctions/damages
- risk mitigation by challenging validity and/or work around / non-infringement

The latest expiring LL patents are displayed in Sanity

Launch relevant patents are described in Executive Summary

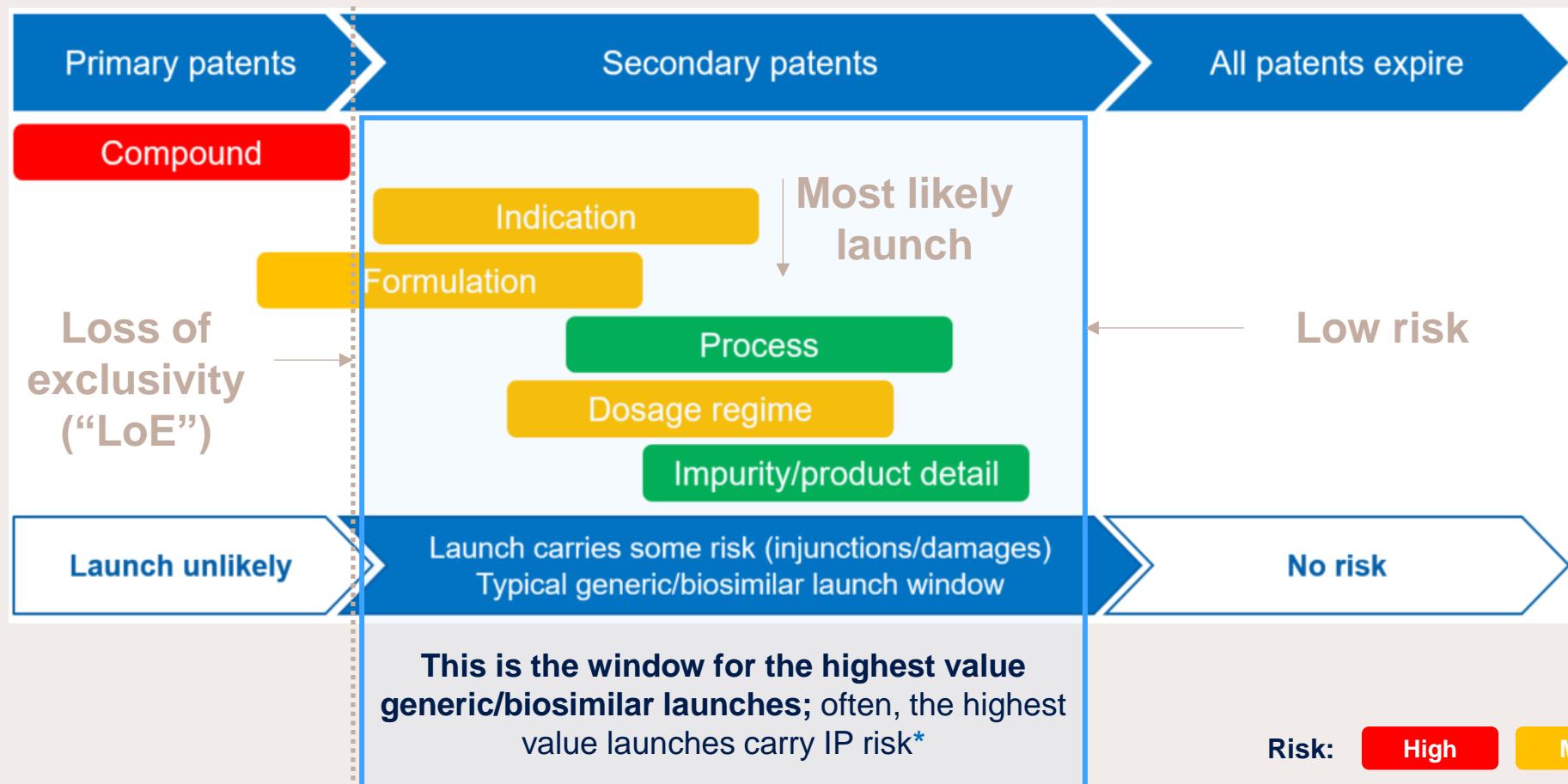
Loss of Exclusivity is a calculated date

LOE =	<ul style="list-style-type: none">▪ Loss of Exclusivity is the earliest, <u>theoretical</u> market entry date. It may not be the actual launch date.▪ LOE is the last expiring of:<ol style="list-style-type: none">a) Regulatory Exclusivity*: OR<ul style="list-style-type: none">• To incentivize the drug development, authorities grant market exclusivity for a certain period (e.g. up to 11 years in EU) from approval• During this period, no other company can get approval for a generic.b) Patent Expiry:<ul style="list-style-type: none">• When drug developers create a new molecule, nucleotide sequence, antibody etc., they can get a patent expiring 20 years after the filing date ("basic patent family").• Plus additional patent term extension up to 5.5 years to compensate a patent holder for the time to receive regulatory approval for a new product.
a) Regulatory	
b) Patent expiry	

LOE can change over time, due to newly granted patents, extensions and exclusivities.

Are there risks for a generic launch at LOE?

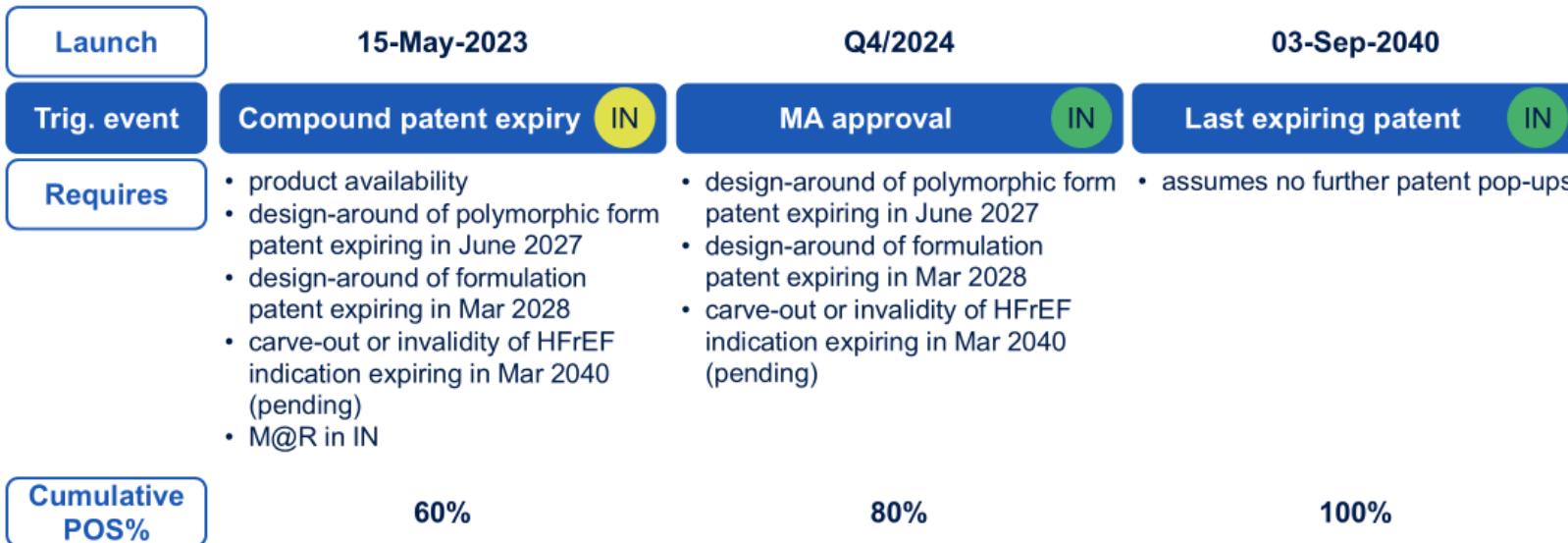
IP risk assessment is *not a yes or no*, it is the risk of launching at a specific date



IP risk assessment presented as „3D slides“

Dapagliflozin BR: Launch at Product Availability

Current - Dapagliflozin BR - September 2022



Privileged & Confidential

PT-400195



Risk to manufacture for this launch date and country of manufacture

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What are the 3Ds and what to take from it?

Best case

- Earliest theoretical market entry (LOE)
- Product readiness

Most likely

- Target launch date
- Date for financial planning
- Subject to change
- “Launch at risk”

Low risk

- All patents expired
- No competitive advantage

POS = Probability of Success to launch and stay in the market at respective timepoint (in % or):

LOW

Medium

High

3D Slides now available in Sanity

	Best Case	Most Likely	Lowest Risk
Manufacturing Country	IN	IN	IN
Manufacturing Risk	●	●	●
Launch Date	15-May-2023	Q4/2024	03-Sep-2040
Launch Triggering Event	Compound patent expiry	MA approval	Last expiring patent
Requires	product availability design-around of polymorphic form patent expiring in June 2027 design-around of formulation patent expiring in Mar 2028 carve-out or invalidity of HFrEF indication expiring in Mar 2040 (pending) M@R in IN	design-around of polymorphic form patent expiring in June 2027 design-around of formulation patent expiring in Mar 2028 carve-out or invalidity of HFrEF indication expiring in Mar 2040 (pending)	assumes no further patent pop-ups
POS	60%	80%	100%

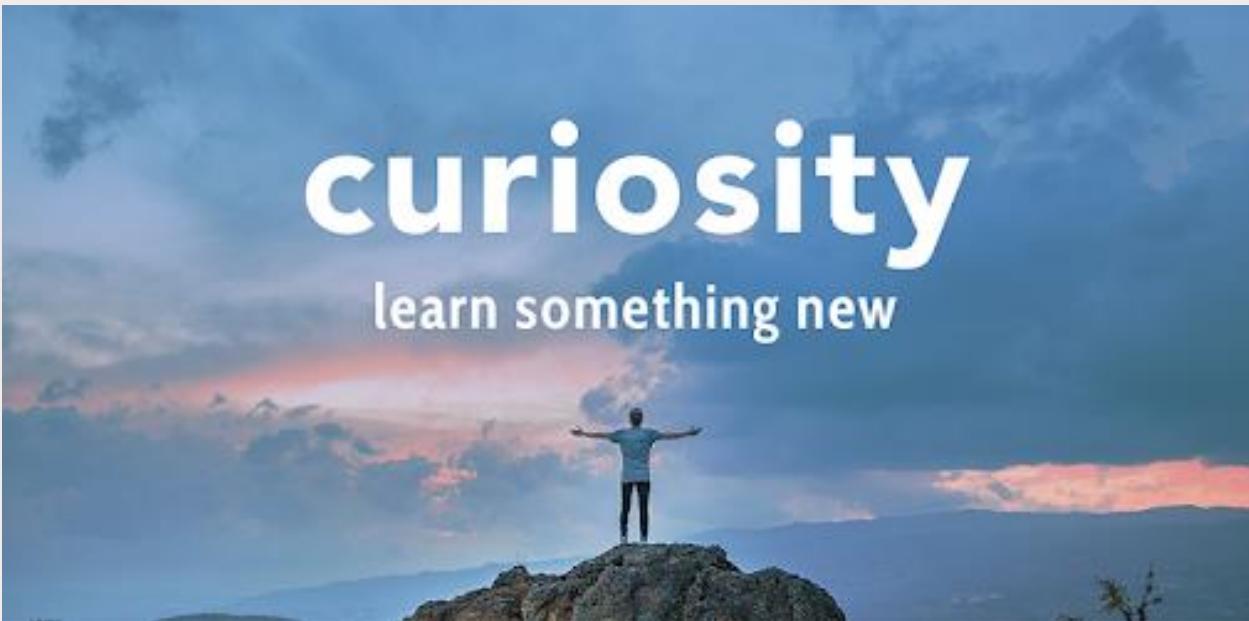


3D slide now also displayed in Sanity

PPT slide desks from

eagleIP
 LANDSCAPE

Q&A



curiosity
learn something new

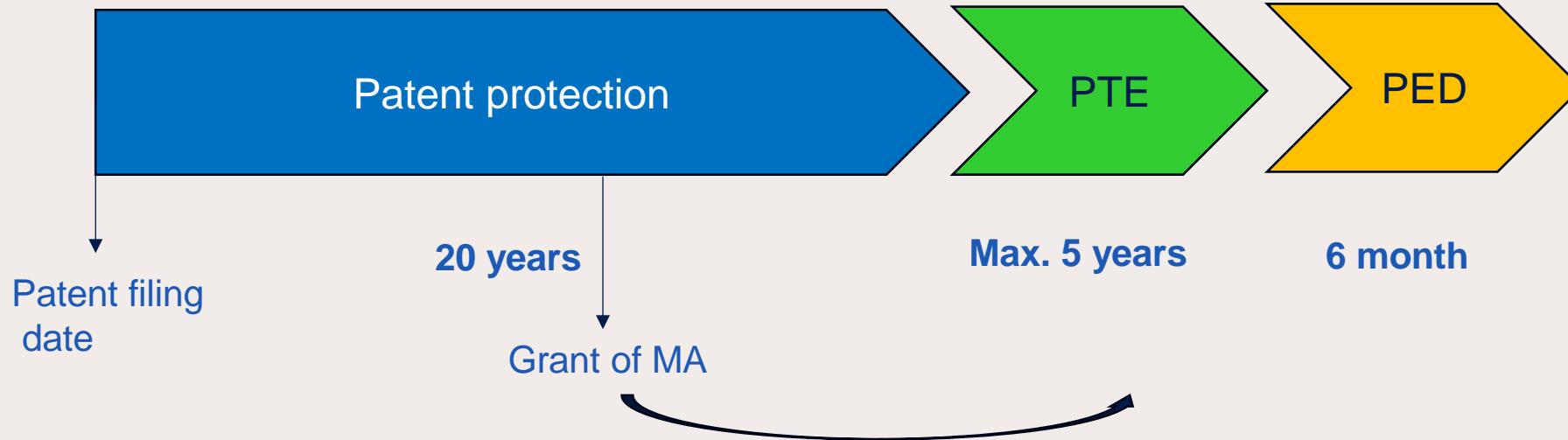
Get/IPknowhow

S A N D O Z

Backup

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Patent extension in the pharmaceutical field



- Rewards to compensate MA procedure and for fulfilling pediatric studies
 - Individual national rights granted on top of a patent
 - Same claim scope as underlying patent
 - Own legal status and expiry date (reflected in Sanity)
- => They can result in a shift of our LOE date

SPC = Supplementary Protection Certificate
PTE = Patent Term Extension
PED = Pediatric Exclusivity



eagleIP LOE

Imported via
Interface

calculated
based on

Maintained by IP

regulatory
exclusivities

patent
exclusivities

Market Formation

in Sanity

LOE or

Maintained by Portfolio

settlements

GX market
assumptions