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# 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



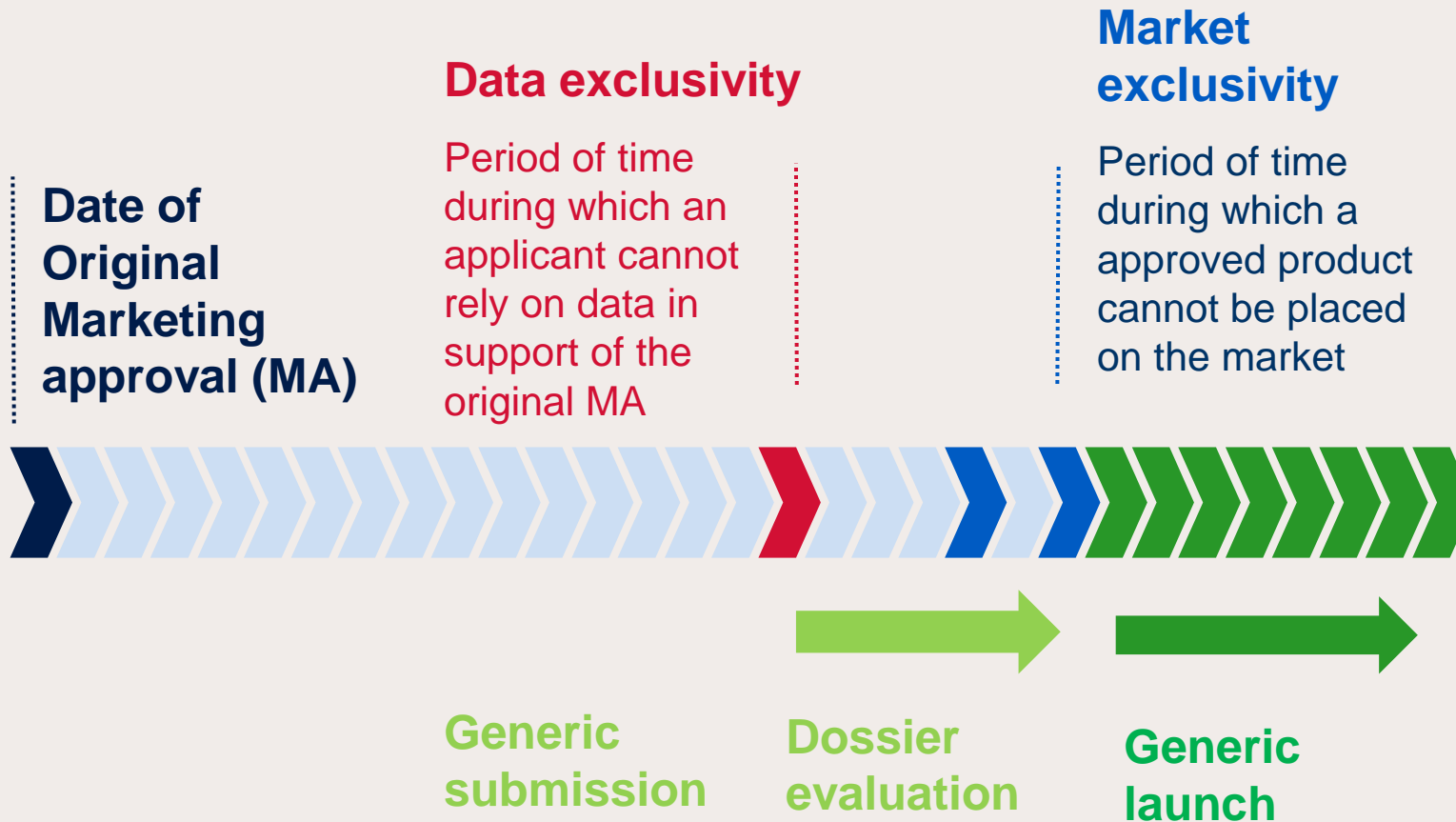
- Clinical studies to show that a medicine is safe and efficacious
- Regulatory approval

## Medicine available for patients



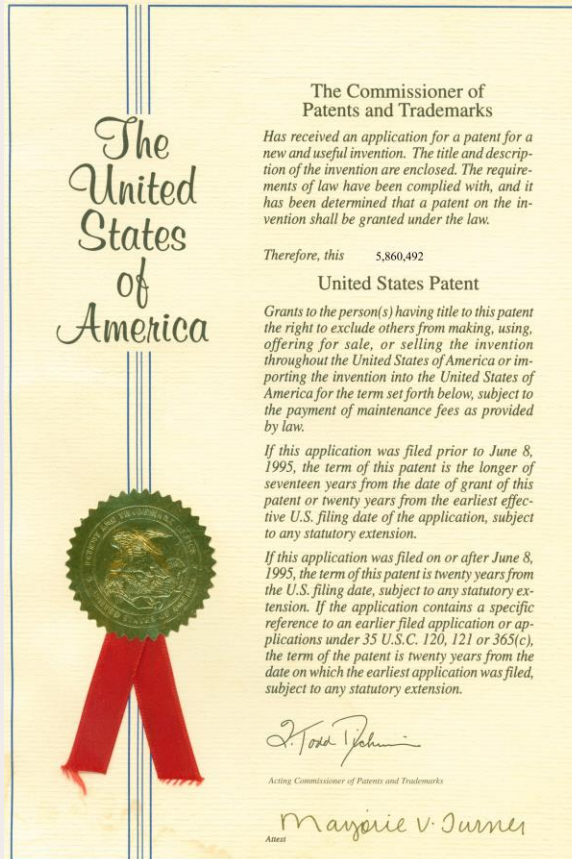
- New medicinal products enter the market after extensive, time-consuming and cost-intensive research, studies and regulatory procedures

# 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	-

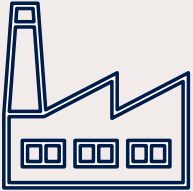
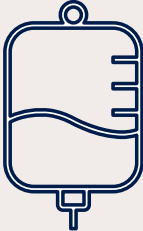

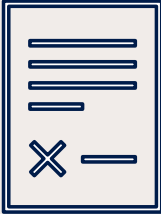
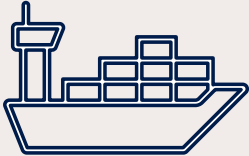
# Patent protection



- 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

The latest expiring LL patents are displayed in Sanity



## 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

Launch relevant patents are described in Executive Summary

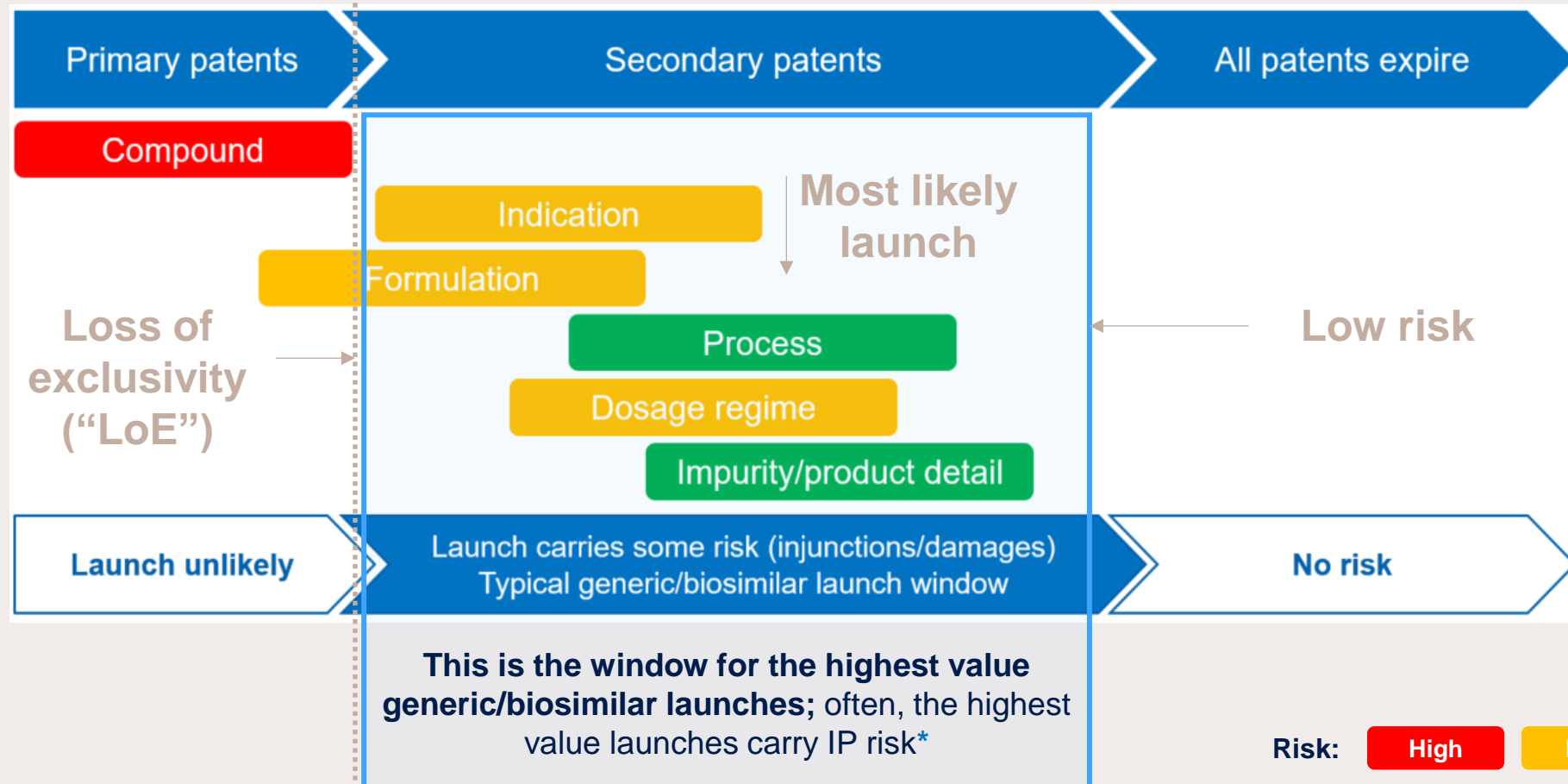
# Loss of Exclusivity is a calculated date

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

Launch	15-May-2023	Q4/2024	03-Sep-2040
Trig. event	Compound patent expiry <span>IN</span>	MA approval <span>IN</span>	Last expiring patent <span>IN</span>
Requires	<ul style="list-style-type: none"> <li>• product availability</li> <li>• design-around of polymorphic form patent expiring in June 2027</li> <li>• design-around of formulation patent expiring in Mar 2028</li> <li>• carve-out or invalidity of HFrEF indication expiring in Mar 2040 (pending)</li> <li>• M@R in IN</li> </ul>	<ul style="list-style-type: none"> <li>• design-around of polymorphic form patent expiring in June 2027</li> <li>• design-around of formulation patent expiring in Mar 2028</li> <li>• carve-out or invalidity of HFrEF indication expiring in Mar 2040 (pending)</li> </ul>	<ul style="list-style-type: none"> <li>• assumes no further patent pop-ups</li> </ul>
Cumulative POS%	60%	80%	100%

Privileged & Confidential

PT-400195

BR

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



# Q&A



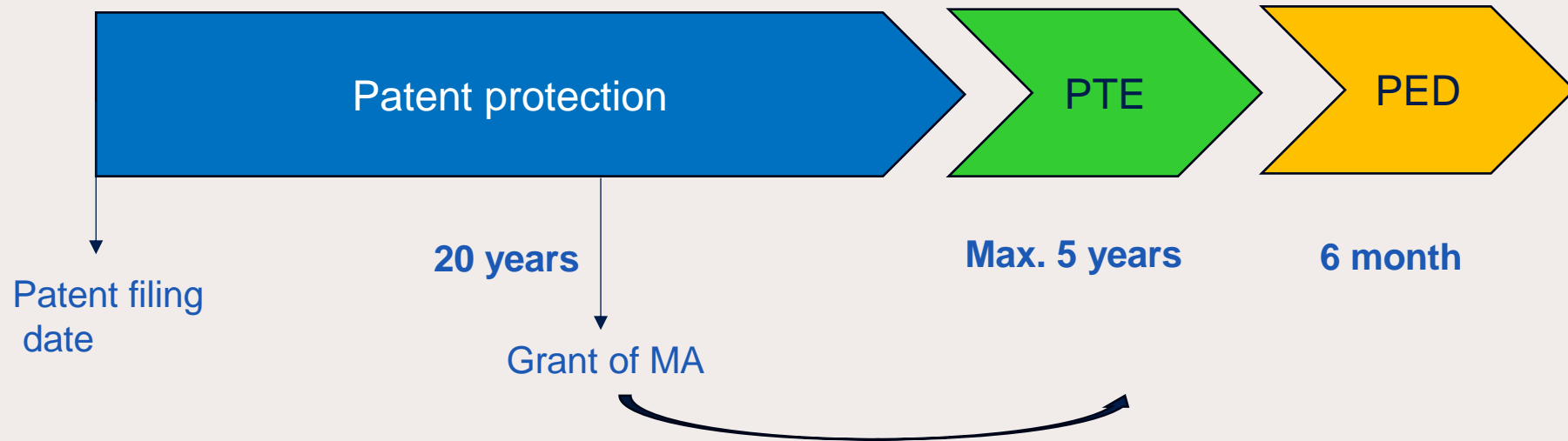
**Get/IPknowhow**

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**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

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## eagleIP LOE

Imported via  
Interface

Maintained by IP

calculated  
based on

regulatory  
exclusivities

patent  
exclusivities

## Market Formation

in Sanity

Maintained by Portfolio

LOE or

settlements

GX market  
assumptions