Case study 1

Name and type of the product	Cosentyx® (secukinumab)
Product developer (company name)	Novartis
IP incentive concerned	10-year Regulatory Data Protection period (RDP) for the first EU approval of Cosentyx in psoriasis 5-year SPC on the patent protecting the invention of secukinumab
Justification/added value	RDP to January 2025 to protect the data generated in the costly clinical trials from being used for development of generic products SPC to compensate for the delay in approval that was due to significant time to conduct the complex clinical trials. If granted, the SPC potentially extends the protection term to January 2030. Ongoing studies in children with psoriasis may be rewarded with a 6-month extension of the SPC, until July 2030.

Case study 2

Name and type of the product	Ilaris® (canakinumab)
Product developer (company name)	Novartis
IP incentive concerned	Regulatory Data Protection (RDP) SPC granted
Justification/added value	RDP until 2019 to protect the data generated in the costly clinical trials from being used for development of generic products. Additional year RDP for the approval with Gouty Arthritis until October 2020. SPC until October 2024 to compensate for the significant time needed to conduct the complex clinical trials. Novartis has complied with the requirement for a PIP by doing paediatric studies and have consequently applied for the paediatric extension on the SPC until April 2025.

Case study 3

Name and type of the product	Blincyto (blinatumomab)
Product developer (company name)	Amgen (previously Micromet)

IP incentive concerned	All
Justification/added value	Research on blinatumomab started in 1993 by a spin-off of the University of Munich, Institute of Immunology – Micromet. In 2006 Micromet moved to the US to access capital, but unable to bring its discovery to the market (despite capitals received and partnerships with several pharmaceutical companies). Amgen invested its capital to purchase Micromet in 2012. The capital was risked, because the company believed in the science of the molecule and in an IP framework, which guaranteed that the investment could be recouped.

Case study 4

Name and type of the product	Imlygic (talimogene laherparepvec)
Product developer (company name)	Amgen (previously BioVex)
IP incentive concerned	All
Justification/added value	Research on talimogene laherparepvec started in 1999 by a spin-off of the University College London, Department of Structural and Molecular Biology – BioVex. In 2006 BioVex moved to the US to access capital, but unable to bring its discovery to the market (despite capitals received and partnerships with several pharmaceutical companies). Amgen invested its capital to purchase BioVex in 2012. The capital was risked, because the company believed in the science of the molecule and in an IP framework, which guaranteed that the investment could be recouped.

Case study 5

Name and type of the product	Hemangiol
Product developer (company name)	Pierre Fabre Dermatologie
IP incentive concerned	EMA's paediatric-use marketing authorisation (PUMA) scheme.
Justification/added value	PUMA is a dedicated marketing authorization that covers

	the indication(s) and appropriate formulation(s) for medicines developed exclusively for use in the paediatric population. In the absence of patents, this scheme provides key incentives for manufacturers to develop and market a drug for paediatric patients.

Case study 6

Name and type of the product	Buccolam
Product developer (company name)	Shire Services BVBA
IP incentive concerned	EMA's paediatric-use marketing authorisation (PUMA) scheme.
Justification/added value	PUMA is a dedicated marketing authorization that covers the indication(s) and appropriate formulation(s) for medicines developed exclusively for use in the paediatric population. In the absence of patents, this scheme provides key incentives for manufacturers to develop and market a drug for paediatric patients.