



EPTP Challenges for Global Bio-Pharmaceutical Companies

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MLL MEYERLUSTENBERGER LACHENAL FRORIEP



Summary

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Background: Biogen

We pioneer neuroscience and drive innovation to defeat the most complex and devastating diseases

1978 Founded

2 Nobel Laureates part of the Founders

80+ Countries receive our products

100% Renewable power commitment

3 Manufacturing sites in North Carolina and Switzerland***

8,725 Employees Worldwide*

\$10.2B In revenues in 2022

263k L Of bioreactor capacity worldwide**

40 Direct affiliate markets

* Biogen data on file as of Dec. 31, 2022.

** Includes anticipated capacity of Solothurn, Switzerland.

*** Includes Solothurn, Switzerland. First gene therapy manufacturing facility in RTP, North Carolina expected to be operational by the end of 2023.

Confidential and Proprietary

As we look to the future, we're building a multi-franchise business

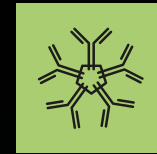
Our strategy is focused on driving the next wave of growth in four priority areas, with a strong foundation and unparalleled capabilities.



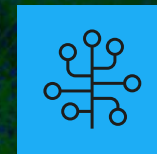
Neuroscience
Expanding on Biogen's leadership in neuroscience with a diversified pipeline



Biosimilars
Providing patient access to innovative medicines and contributing to healthcare sustainability



Specialized Immunology
Delivering first-in-class and best-in-class lupus therapies



Digital Health
Accelerating efforts to build complementary digital solutions and technologies to potentially predict, measure and prevent disease

Our mission is to pioneer neuroscience and drive innovation to defeat the most complex and devastating diseases



<100K

Patients on Avonex WW

AVONEX

1978-2003

World leader in recombinant DNA technology



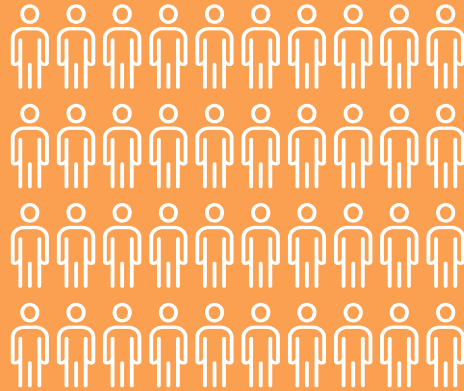
~200K

Patients on MS Tx WW

AVONEX
TYSABRI
RITUXAN

2003-2010

World leader in monoclonal antibodies



~400K

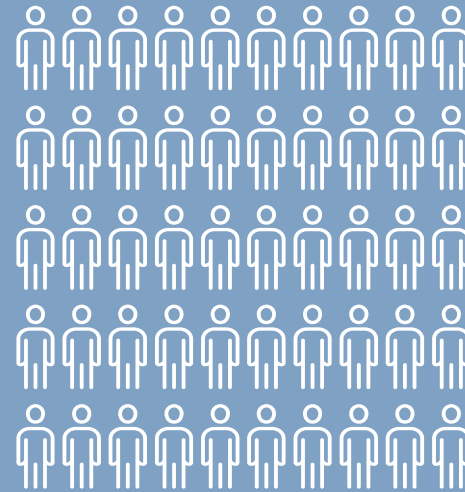
Patients on MS & Hem. WW

AVONEX
PLEGRIDY
TYSABRI
TECFIDERA

RITUXAN
ALPROLIX
ELOCTATE
FAMPYRA

2011-2015

World leader in MS and hemophilia therapies



>500K

Patients on AD, MS, SMA & Biosimilars

ADUHELM
AVONEX
PLEGRIDY
TYSABRI
TECFIDERA
VUMERITY

SPINRAZA
RITUXAN
GAZYVA
BIOSIMILARS
FAMPYRA

2016-2021

World leader and pioneers in neuroscience

Millions of patients

~18

products +

>15

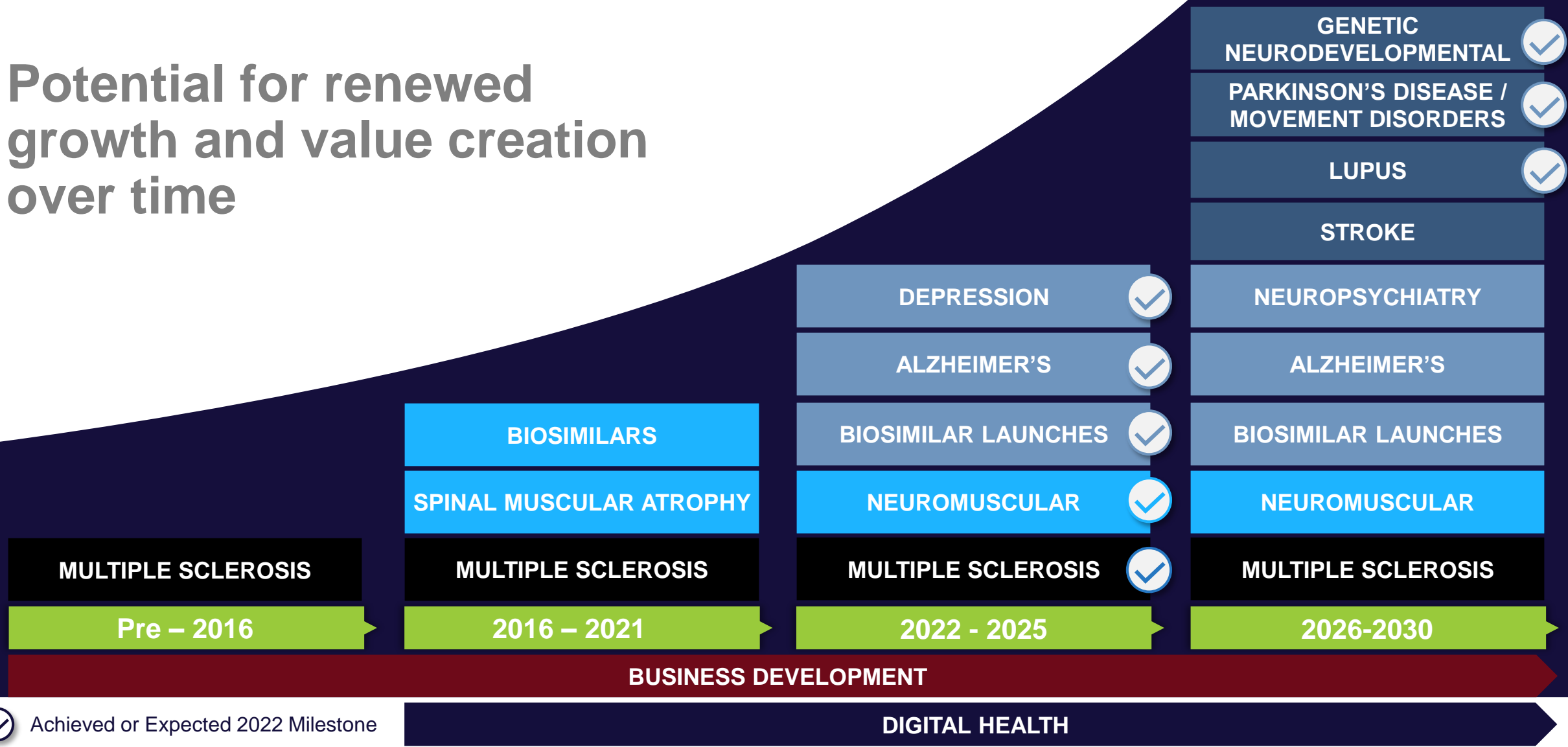
potential additional product launches

2022 -2030

World leader and pioneers in neuroscience and a multi-franchise business



Potential for renewed growth and value creation over time



✓ Achieved or Expected 2022 Milestone



MLL

Background

MLL Legal

MLL MEYERLUSTENBERGER LACHENAL FRORIEP

About MLL Legal

150+

talented lawyers

52

partners in total

18

core services

13

female partners



About MLL Legal

MLL Legal is one of the leading law firms in Switzerland with offices in Zurich, Geneva, Zug, Lausanne, London and Madrid. We advise our clients in all areas of business law and stand out in particular for our first-class industry expertise in technical-innovative specialist areas, but also in regulated industries.



International Scope

We provide bespoke, cross-border advice to Swiss and international clients. Our multilingual team skilfully navigates different cultures and market conditions.



Legal Excellence

Highly ranked by all major international legal directories, we use our recognized expertise and solid legal knowledge to achieve the best results.



Adaptive Teams

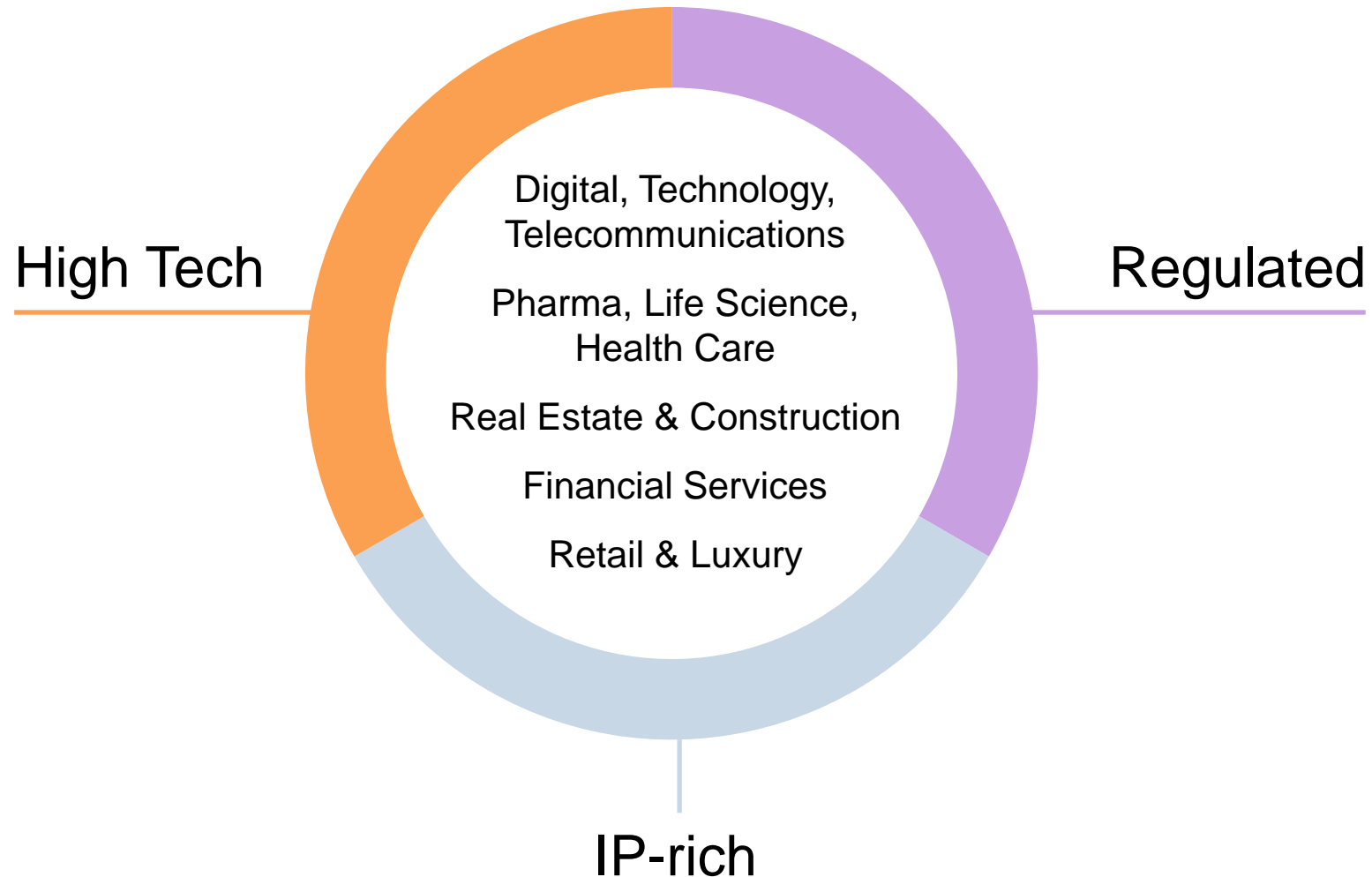
We are a fully integrated firm with an interdisciplinary mindset and a strong team spirit. Our ad-hoc flexibility allows us to scale our resources based on client needs.



Diversity and Plurality

Diversity and plurality of thought are engraved in our firm's culture and create the independence of mind that clients expect from their trusted advisors.

Our Strategic Positioning and Strength: Intersection of high tech, IP-rich and regulated industries

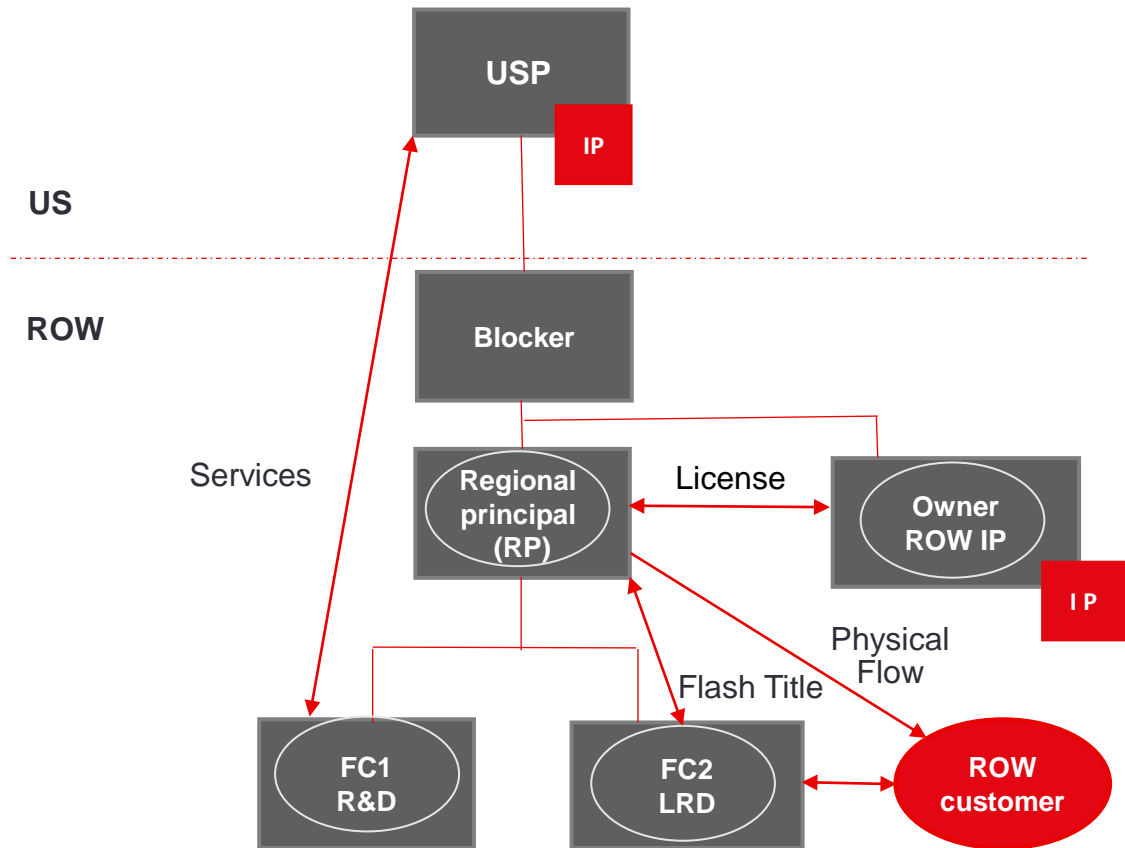




Challenges for Centralized Models DEMPE function

Impact on Incubator Structures (Offshore IP)
Traditional US-Outbound Structure: Transfer of IP to ROW Owner

Traditional US-Outbound Structure with Incubator



Characteristics

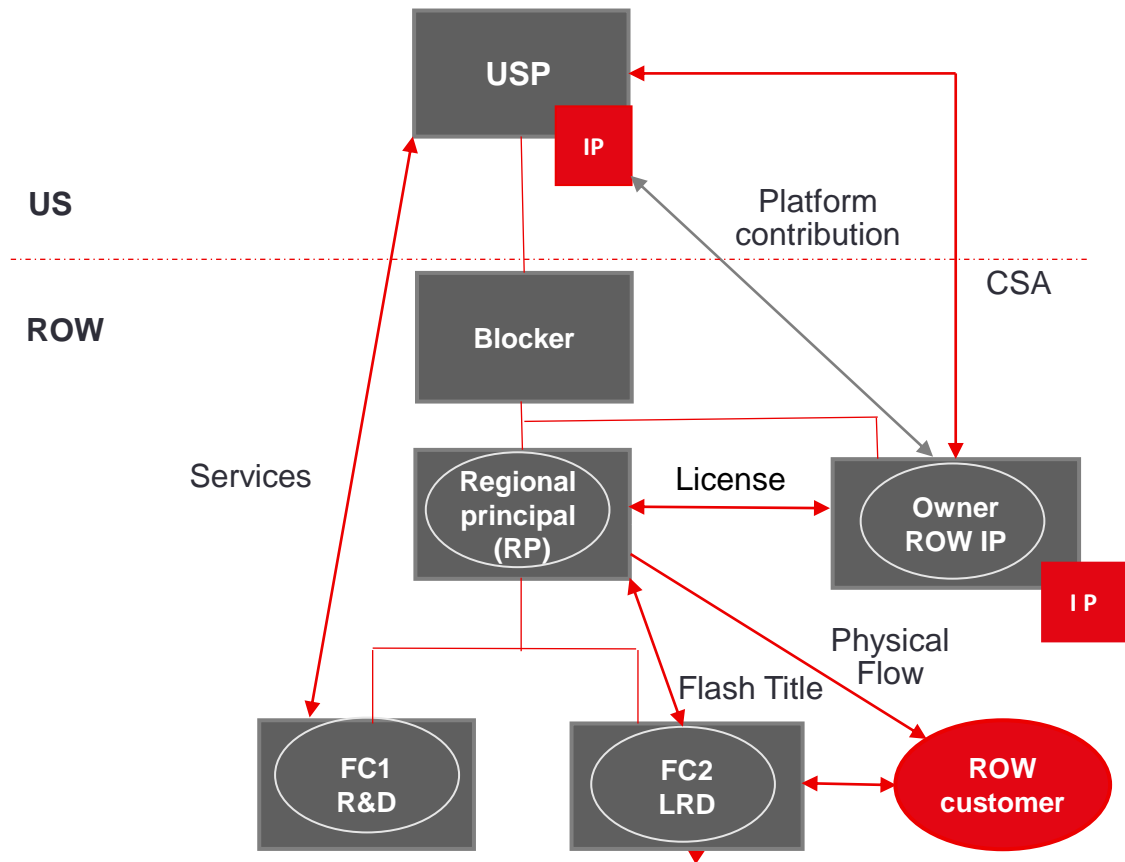
- Segregation of the markets
- Blocker
- ROW IP often held offshore
- IP in-licensed to RP
- Distribution via Commissionaires/LRDs

Profit profile

- RP earns NOM income from ROW market
- Owner ROW IP residual (IP) income from ROW market
- FC1 (most likely cost +)
- FC2 routine returns (NOM)

Issues?

Traditional US-Outbound Structure: Transfer of IP to ROW Owner



Model

- USP and Owner of ROW IP enter into a cost sharing arrangement (CSA)
- Under the CSA, USP and Owner of ROW IP share R&D expenses based on their respective reasonably anticipated benefit (RAB) shares from exploitation of the IP in their assigned territories; as a result of this, each earns the returns from their territory
- Owner of ROW IP makes cost share payments (CSTs) consistent with RP's RAB share
- As part of CSA, USP makes "platform contribution" of existing IP (and other capabilities) for which Owner of ROW IP compensates USP through a platform contribution transaction (PCT) to USP
- Owner of ROW IP sells via FC2 to ROW customer

Profit profile

- RP earns NOM residual (IP) income from ROW market
- RP makes license payments to Owner of ROW IP
- US earns return on PCT

Anticipated/desirable tax profile

- PCT is taxed in the US, qualifies as FDII
- ROW residual income (income from IP) taxed at low rate locally, subject to GILTI in US;
- Various non-US anti-abuse rules (e.g., ATAD) are not triggered?
- Ability to counter foreign country assertions of entitlement to greater profit?



Triggers for Implementing Substance-based Structures

Triggers for implementing substance-based structures

DEMPE functions (value-creating functions)

- Associated enterprises performing important value-creating functions related to the development, enhancement, maintenance, protection and exploitation of the intangibles can expect appropriate remuneration

Control over risk

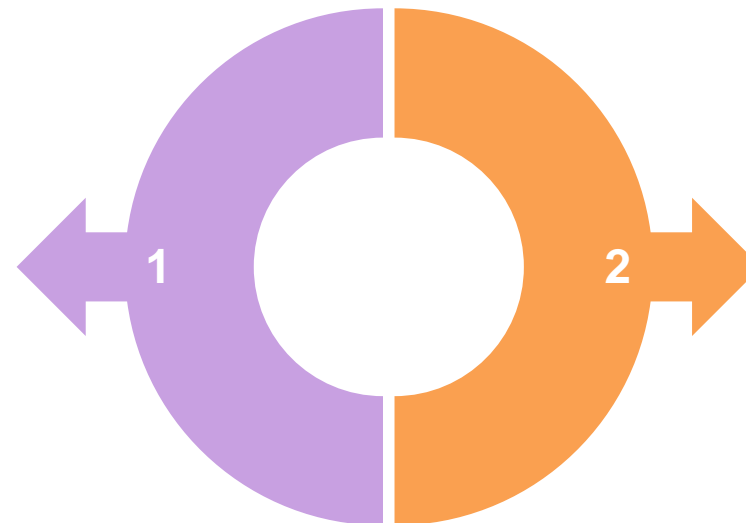
- An associated enterprise assuming risk in relation to the DEMPE functions of the intangibles must:
 1. Exercise control over the risks
 2. Have the financial capacity to assume the risks

Key principles of income allocation under BEPS

- Arm's-length pricing based on contractual relations and actual conduct of the parties
- Alignment of profit allocation and value creation, i.e., allocation of major portion of profits to the entities that perform and control the DEMPE functions

Inconsistencies in existing operating model

BEPS requires alignment between business realities and tax outcomes



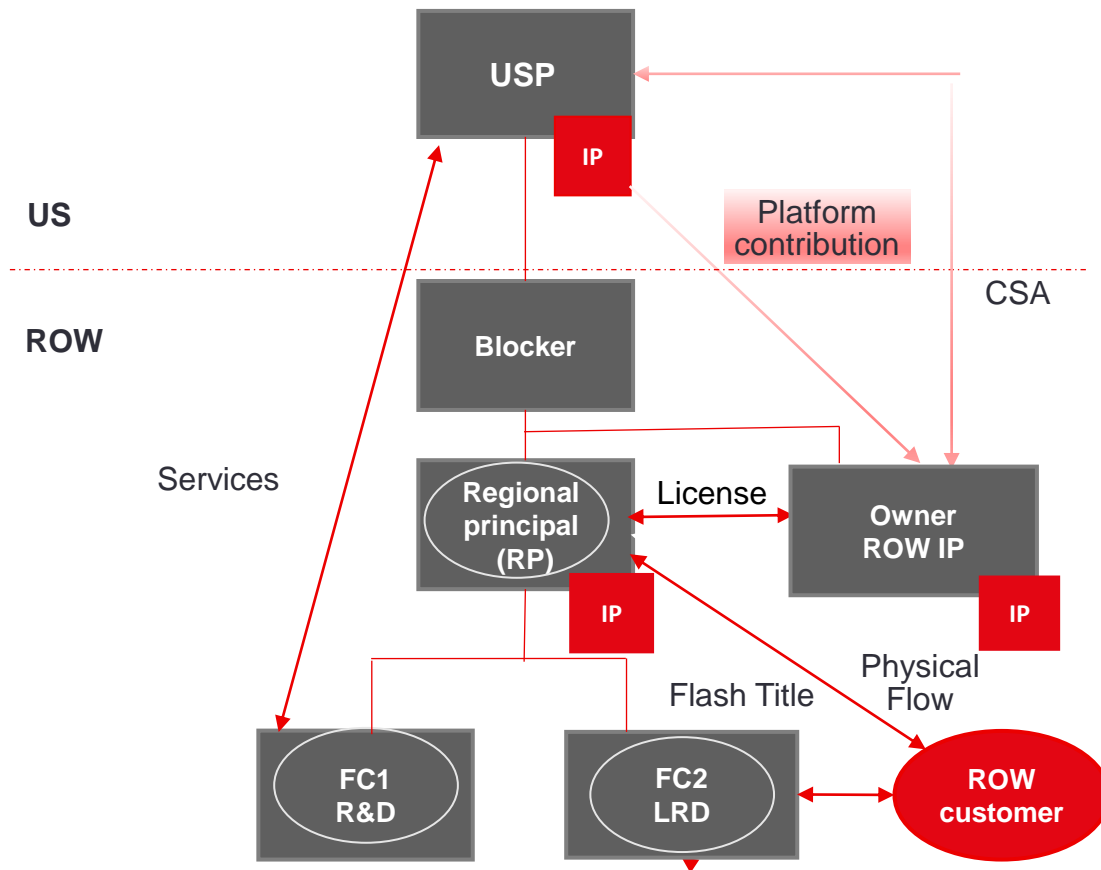
New business changes you are planning

BEPS influences business options



Traditional US- Outbound Structure: Impact of Anti- Hybrid rules

Traditional US-Outbound Structure: Impact of Anti-Hybrid rules



Model

- Owner of ROW IP dividends the respective IP to Blocker
- Blocker contributes respective IP into RP
- USP and RP enter into a cost sharing arrangement (CSA) for respective IP
- Under the CSA, USP and Owner of ROW IP share R&D expenses based on their respective reasonably anticipated benefit (RAB) shares from exploitation of the IP in their assigned territories; as a result of this, each earns the returns from their territory
- RP makes cost share payments (CSTs) consistent with RP's RAB share for the respective IP

Profit profile

- RP earns NOM residual (IP) income from ROW market and residual income on the respective IP
- Owner ROW IP residual (IP) income from ROW market with the exclusion of the respective IP

Anticipated/desirable tax profile

- ROW residual income (income from IP) taxed at low rate locally, subject to GILTI in US;
- Respective anti-abuse rules (e.g., UK anti-hybrid rules) are not triggered
- Ability to counter foreign country assertions of entitlement to greater profit?

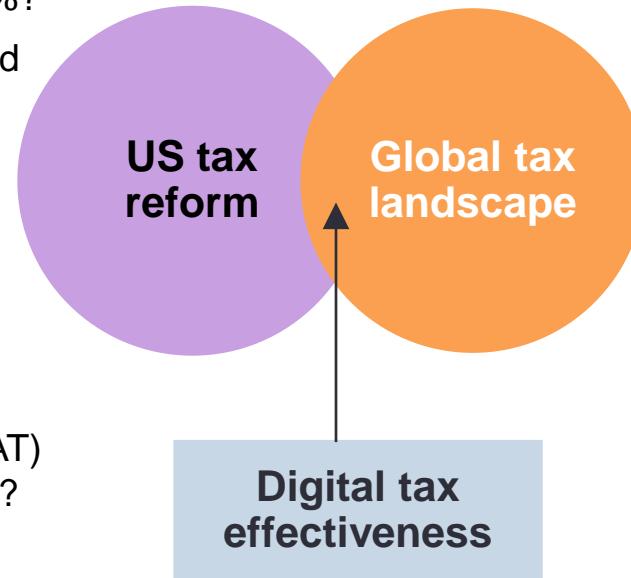


Overview of Key Global Drivers of IP Alignment

Overview of key global (digital) drivers of IP alignment

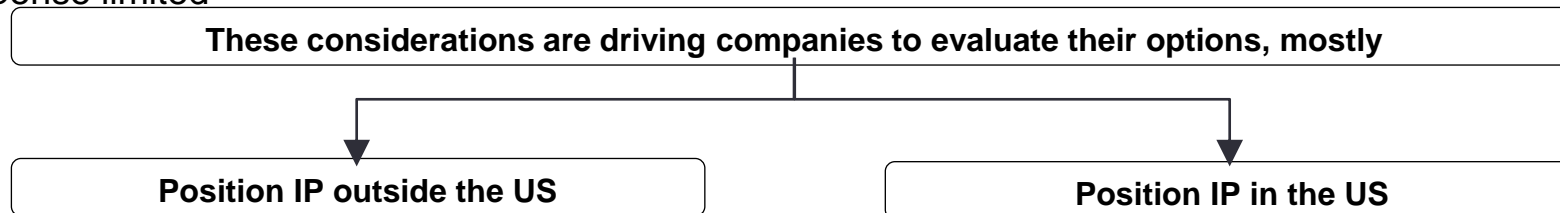
US tax reform:

- Lower existing rates or future rates to increase
- Corporate tax rate 21%, 26.5% or 28%?
- Expanded current US tax on controlled foreign corporations (CFCs) under global intangible low-taxed income (GILTI) at 10.5% or 15.0%?
- Eliminate current 10.5% rate on intangible income from foreign sales foreign-derived intangible income (FDII)?
- Base erosion and anti-abuse tax (BEAT) being replaced by SHIELDS or UTPR? results in potential minimum tax rate 21% or 15.0%?
- Interest expense limited



Global tax landscape:

- Increased focus on employee substance to attribute profits from intangibles development, enhancement, maintenance, protection and exploitation (DEMPE)
- Lower tax nexus (PE) standards
- Increasing array of local anti-abuse measures attacking a variety of operating models
- Aggressive Anti-Tax Avoidance Directive (ATAD) and BEPS-oriented agenda in countries of revenue source
- Local incentives are still possible?
- OECD/EU Pillar 2 Minimum tax
- EU, OECD and unilateral country interim actions driving toward turnover taxes on various digital business models?
- Pillar one / Pillar two



Overview of key global drivers of IP alignment (cont.)

Assess key value drivers

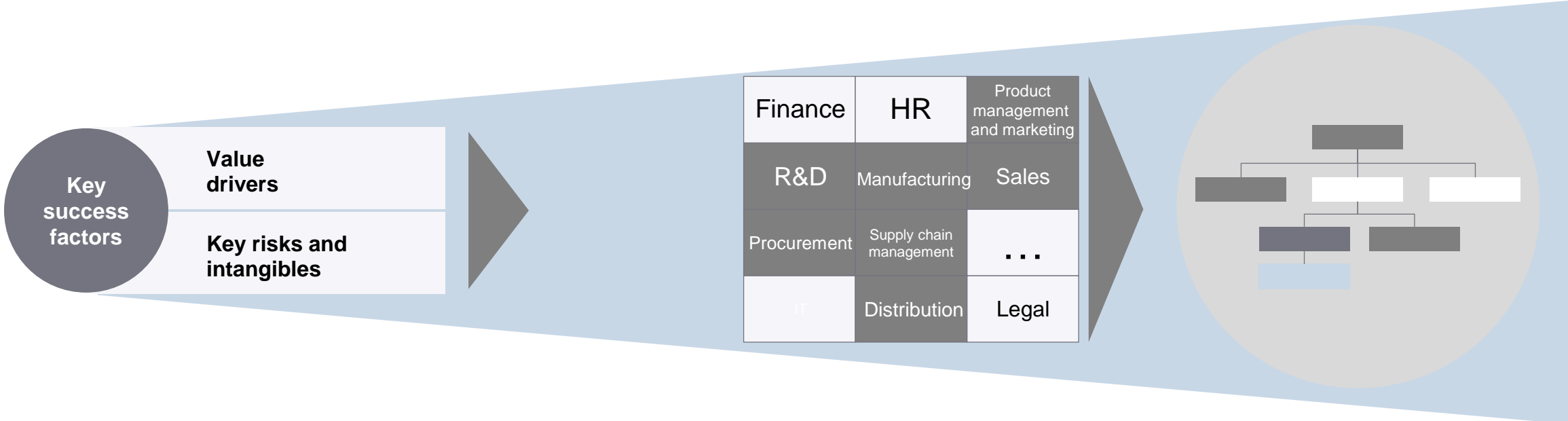
- Economic risks and value drivers are critical levers to be controlled to achieve and maintain success

Define critical processes

- Execution of certain critical core business processes and activities impacts the value drivers or risks

Identify roles

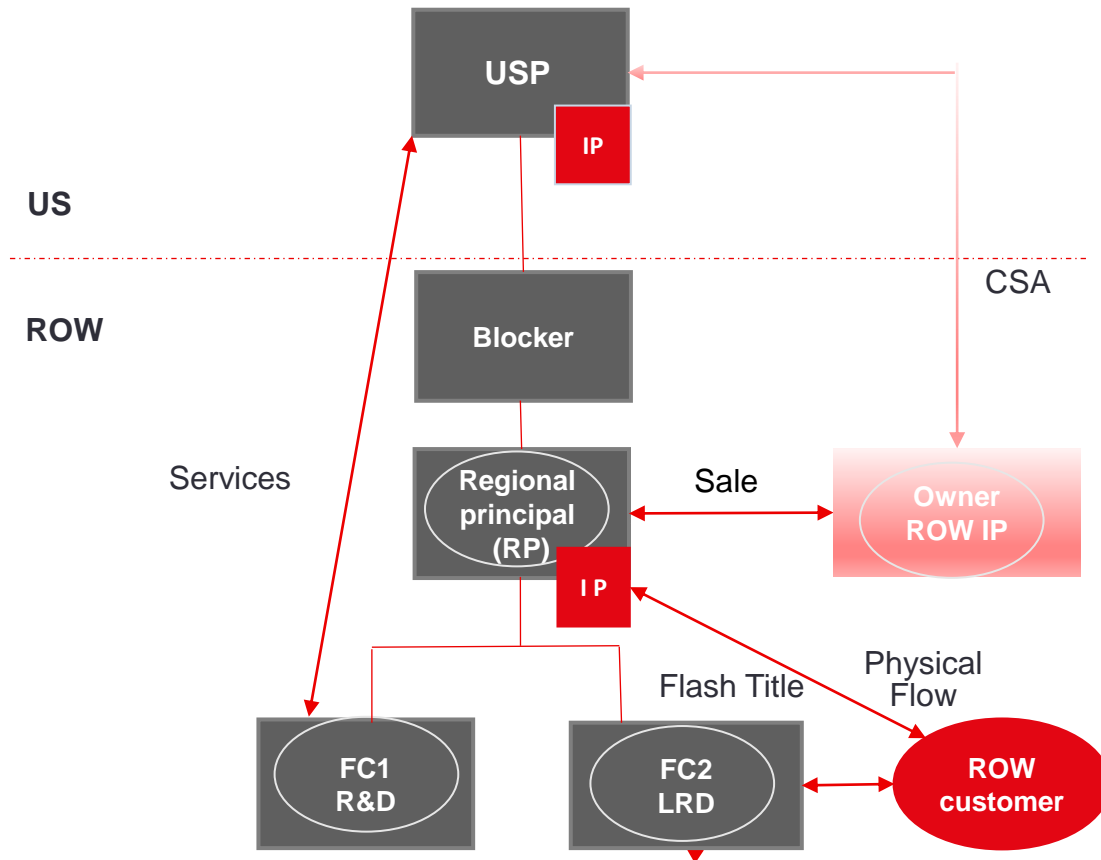
- Roles to perform or manage critical processes and thereby the value drivers and risk





Traditional US- Outbound Structure: Impact of BEPS

Traditional US-Outbound Structure: Impact of BEPS



Model

- Owner of ROW IP sells IP to RP
- USP and RP enter into a cost sharing arrangement (CSA) for all IP
- Under the CSA, USP and RP as Owner of ROW IP share R&D expenses based on their respective reasonably anticipated benefit (RAB) shares from exploitation of the IP in their assigned territories; as a result of this, each earns the returns from their territory

Profit profile

- RP earns residual income on all IP
- Owner ROW IP gets purchase price or interest income on loan check impact of GLOBE

Anticipated/desirable tax profile

- ROW residual income (income from IP) taxed at low rate locally, subject to GILTI in US;
- BEPS rules are not triggered
- Ability to counter foreign country assertions of entitlement to greater profit?



Operating models impacted by BEPS Action 7

Operating models impacted by BEPS Action 7

Action 7 broadens the PE definition to address perceived scenarios/arrangements artificially avoiding to create a PE

Commissionaire and similar arrangements (e.g., dependent agent PE)

Facilities owned by principal used for storage or delivery or purchasing inventory (e.g., warehouses)

Inventory owned by principal held at facilities used for storage or display or delivery or processing (e.g., toll-manufacturers, consignment stock)

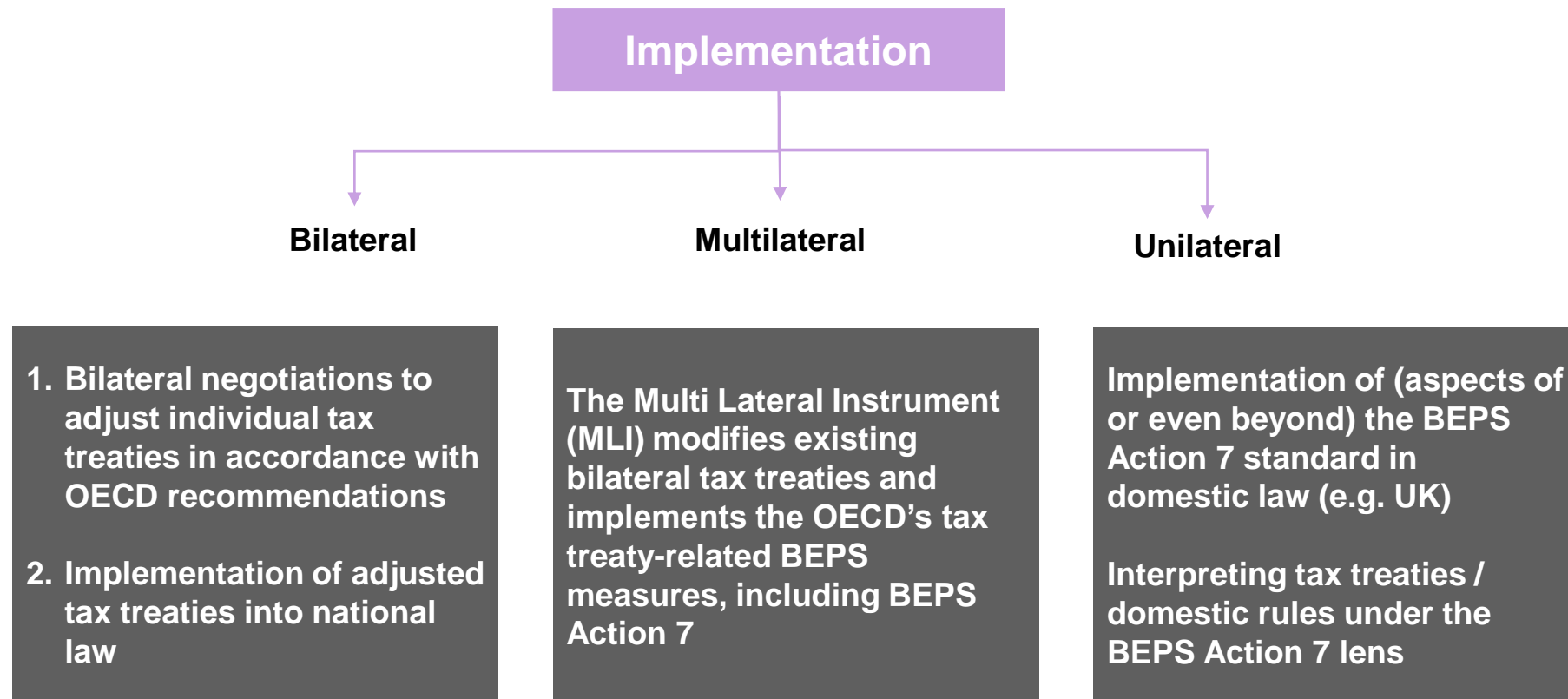
Models where contracts for projects or services are allocated to and performed by several related group entities

Models where functions that could be seen as “complementary business activities forming part of a cohesive business operation” are carried out by group entities at the same or different place(s) in one country

Taxable presence in the digitalized economy

Implementation of BEPS Action 7

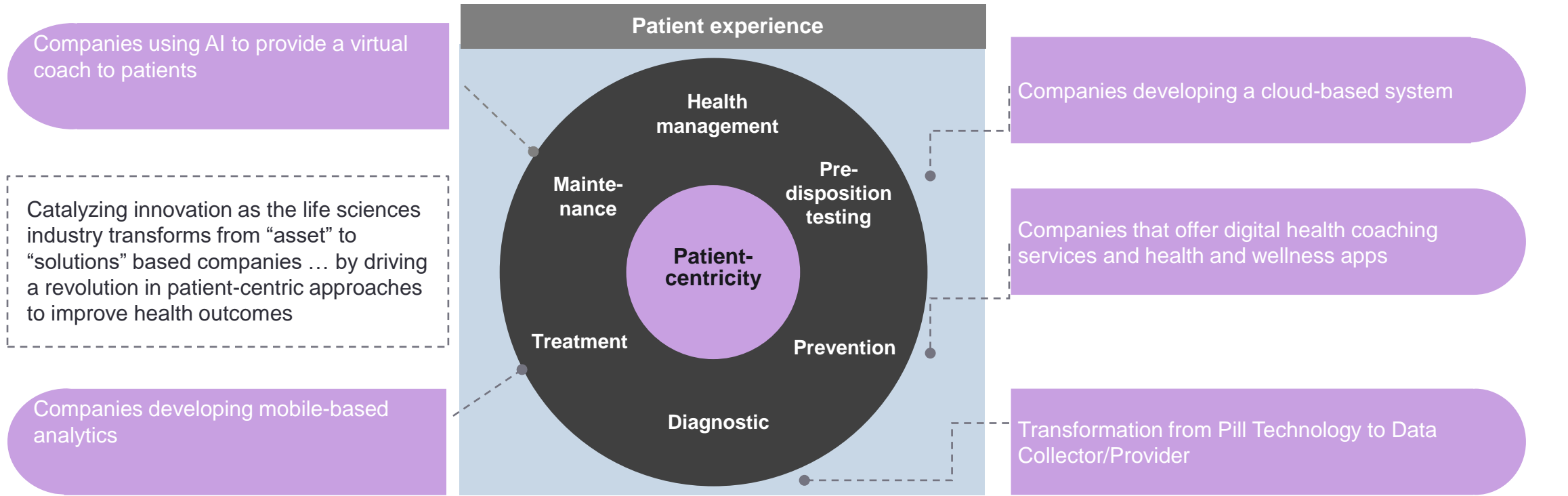
Implementation of BEPS related measures into tax treaties





Life Science Companies Going Beyond Pill Technology to an Enabled Health

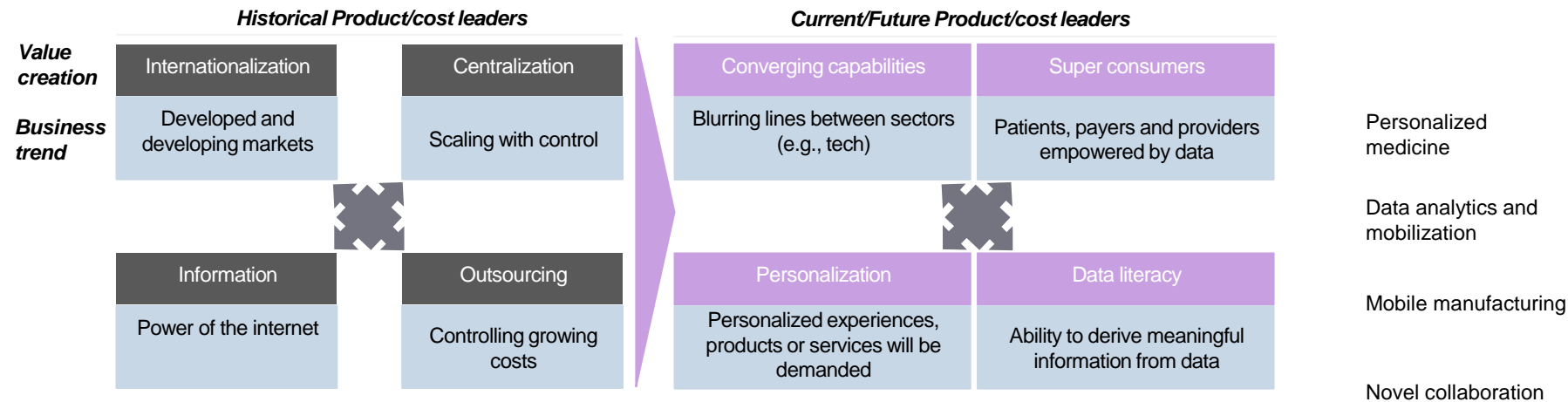
Life sciences companies going beyond pill technology to an enabled health solution



<p>Technologies</p> <ul style="list-style-type: none"> • Wearables, sensors, IoT • Remote monitoring technologies • Gamification • Social media • Online platforms 	<ul style="list-style-type: none"> • Artificial intelligence • Advanced analytics • Smartphone apps • 3D printing 	<p>Watch-outs</p> <ul style="list-style-type: none"> • Data interoperability • Regulatory/legal issues • Data privacy • Trust gap
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Trends and operating model impacts life sciences industry

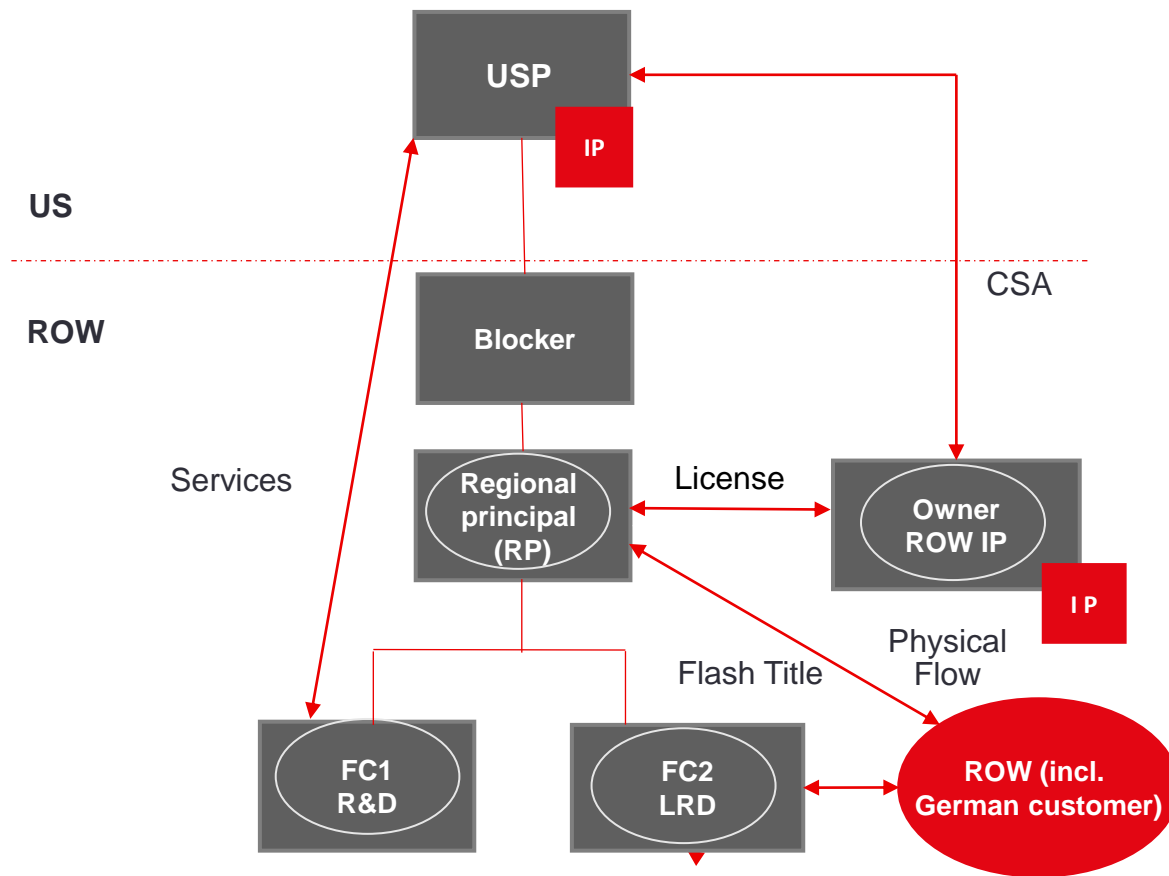
- Today, globalization, digitalization, and an ever-changing regulatory environment are driving new business-led initiatives that will shape the operating models of tomorrow
- With the passing of the Tax Cuts & Jobs Act (TCJA) global tax planning for life sciences companies ceased to be intuitive. Combined with international initiatives that make the taxing powers of countries further reaching and some methods for managing tax costs less effective, a different approach to creating value through tax is needed
- Furthermore, with the advent of US trade reform and global reactions as well as Brexit and other trade disruptors, life sciences companies are evaluating their supply chains with the goal of mitigating increased duties. Combined with US and international tax initiatives, such as BEPS 2.0, supply chains are at the center of driving efficiencies and mitigating costs.
- Business strategies, operating effectiveness and shareholder value is at risk. More than ever, life sciences companies need to plan and operate by aligning business and tax objectives through integrated decision-making and adopting a 'total- shareholder-return' perspective





Traditional US- Outbound Structure with in-licensed IP under German extraterritorial IP considerations

Traditional US-Outbound Structure with in-licensed IP under German extraterritorial IP considerations



Where a non-German person licenses or sells **IP** that is either **registered in a German public register** or where IP is **exploited in a German permanent establishment (p.e.)**, Germany under domestic law can claim a taxing right. Likewise, where technical or commercial **know-how** is granted for **use in Germany**, a German taxing right can exist.

In the case of **IP licensing**, the tax would be levied via WHT (15.825%) to be withheld by the royalty payor, even if that person is not a German tax resident.

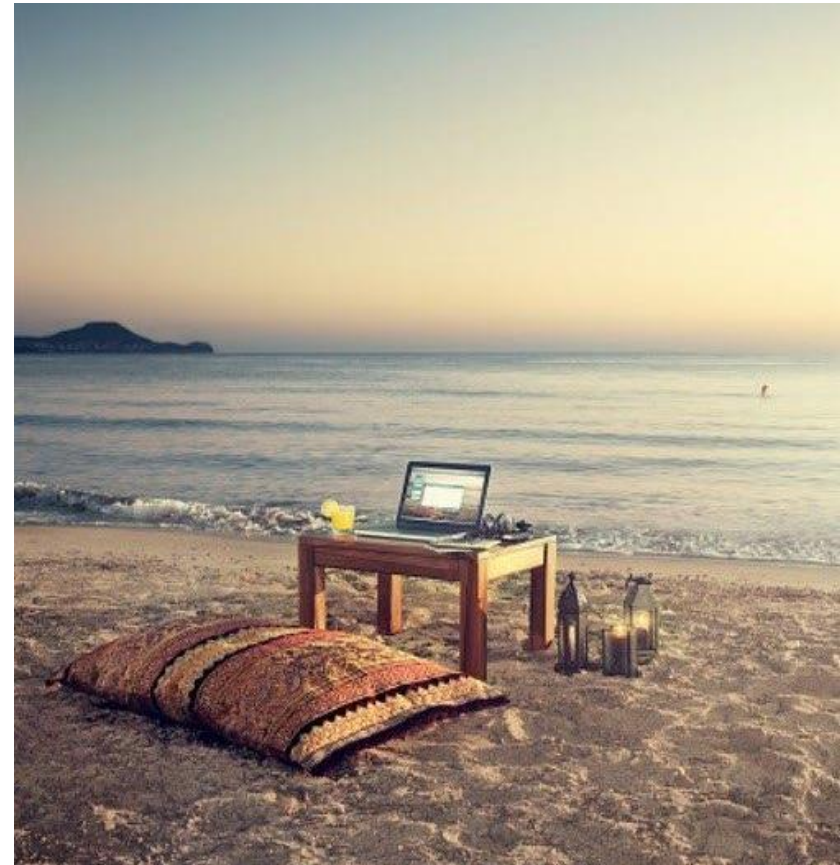
- ▶ Abolished for transactions btw. unrelated parties retroactively.
- ▶ For related parties transactions the rule is maintained, unless the applicable treaty provides for otherwise (check tightened German anti-treaty shopping rules: Analysis and documentation is needed)

In the case of a **sale of the IP**, the German taxing right would mean that a non-treaty protected IP owner would have to declare a gain on such sale to the German tax authorities via a tax return filing. A gain should be taxable at 15.825% CIT/solidarity levy for a corporate seller. Generally, a treaty-protected IP-owner should not be impacted by this extraterritorial taxation as the gain should be covered by the business income article.



Tax Challenges: Work from Home

Tax challenges: Work from Home Office



What constitutes a p.e. from a tax perspective?

- A p.e. is a fixed place of business in which the business activity of a company is carried out in whole or in part (Art. 52 para. 2 Federal Direct Tax Law and Art. 5 para. 1 OECD-MA).
- The following elements are essential:
 - Fixed place of business (e.g. office, plant etc.), is inherent to a HO
 - Which is permanently, and not merely temporarily, at the disposal of the enterprise. Does not constitute a p.e. if used occasionally.
 - Qualitatively and quantitatively essential activity performed at the p.e., i.e. the work performed contributes to the value generation of the enterprise (e.g. leadership function, sales activities)
 - Part of the business of the enterprise: since HO is operated by an employee this requirement is always met.

When should WFH model not create a p.e.

- OECD-MC 2017, C(5)-6 ref# 18
“Even though part of the business of an enterprise may be carried on at a location such as an individual’s home office, that should not lead to the automatic conclusion that that location is at the disposal of that enterprise simply because that location is used by an individual (e.g. an employee) who works for the enterprise. Whether or not a home office constitutes a location at the disposal of the enterprise will depend on the facts and circumstances of each case.”
- No p.e. assumed:
 - If the carrying on of business activities at the HO is so intermittent or incidental that the HO will not be considered to be a location at the disposal of the enterprise.
 - Individual has an office available at the location of the enterprise and uses the HO on an occasional basis (say 1 day per week).
 - If the activity performed at the HO does not contribute to the value creation of the enterprise.

When could WFH model create a p.e.?

- OECD MC- 2017, C(5)-6 ref# 18:
“Where, however, a home office is used on a continuous basis for carrying on business activities for an enterprise and it is clear from the facts and circumstances that the enterprise has required the individual to use that location to carry on the enterprise’s business (e.g. by not providing an office to an employee in circumstances where the nature of the employment clearly requires an office), the home office may be considered to be at the disposal of the enterprise.”
- p.e. assumed:
 - HO is used on a frequent basis for meetings with clients
 - HO is used on a permanent basis and employer tolerates the use of HO by the employee
 - Employer does not provide an office at the location of the enterprise

Current status

- Whether a HO creates a p.e. or not is not a black/white decision. There is a broad grey zone in between.
- There are different interpretations, as to what are the decisive factors in determining when HO may constitute a p.e.
- In light of Covid 19 the Tax advisory board to the cantons (SSK) issued an analysis
 - Generally, no fixed place of business
 - Generally, no qualitatively and quantitatively essential activities
 - No aggregation, if employees work in the same canton/community
- However,
 - Such recommendations are not binding
 - Cantons are autonomous as regards cantonal tax laws, unless the Tax Harmonization Law comprises binding rules
 - Cases when a home office becomes a p.e. have already been decided in Germany and Austria. On an international level, a trend can be observed that a HO is more often qualified as a p.e., compared with the Swiss practice.

WFH latest developments

- Switzerland signed on May 31, 2023 the “Framework Agreement for Habitual Cross-Border Teleworking in EU, EEA and Switzerland” which entered into on July 1, 2023 (source: IBFD Tax News Service – 14 June 2023 with further references)
- The Swiss Federal Council launched the consultation proceeding concerning the Federal law on the taxation of mobile working in international relations with date of June 9, 2023 (source: https://fedlex.data.admin.ch/eli/dl/proj/2023/14/cons_1).



Outlook

Overview timeline of future EU developments

Timeline EU development	2021				2022				2023				2024				2025	2026
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1-Q4	Q1-Q4
Foreign Subsidies Regulation		7 May						28 November			12 July							
Pillar Two Directive				22 December				15 December				31 December (IIR)				31 December (UTPR)		
Unshell				22 December							Q3 (TBC)						1 January (TBC)	
DEBRA (on hold)						11 May						31 December	1 January					
Energy Regulation							14 September	6 October	Q4									
DAC8								8 December		Expected in June							31 December	1 January
ETR Publication										Expected in Q2?			Expected in 2024					
Pillar One Directive										Expected in Q2								
DAC9										Expected in Q2?								
WHT Initiative (FAST)										Expected on 28 June								
SAFE											5 July (TBC)							
BEFIT											Expected on 12 September							

Proposal and negotiations

Adoption

Transposition

Entry into effect

Key Contact

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Markus F. Huber joined MLL as partner on 1 July 2017, after retiring from Ernst & Young where he was partner for more than 20 years. He headed the International Tax Services Group at EY for 15 years. Markus F. Huber now has more than 35 years of experience in fiscal law and holds particular in-depth expertise in international corporate tax law, in the area of cross-border transactions and restructurings and other complex tax planning. In addition, Markus advises high net wealth individuals in tax planning. During 2½ years he worked as a Swiss tax lawyer in New York. From 2013 to 2017 Markus Huber was based in Geneva. He is fluent in German, English and French.

«Markus is known and appreciated by clients and colleagues for his excellent technical skills and dedication. Over the years, he built a great reputation in the marketplace and is today seen as one of the leading international tax advisors in Switzerland.»

Chairman of big 4

Thank you for your
time and interest

