



Carmen E. Correa M. LL.M., RTTP
Block Exception Regulations - General Introduction
Nov. 15, 2023, Antwerpen



 **TECHNOLOGY
TRANSFER OFFICE**

Erasmus MC
Universitair Medisch Centrum Rotterdam



AGENDA



- ▶ Legal framework: What are Block Exception Regulations?
- ▶ TTBER
- ▶ R&D BER
- ▶ What if an exception does not apply?

LEGAL FRAMEWORK



- ▶ Article 101 TFEU: anticompetitive agreements between undertakings
- ▶ Article 102 TFEU: abuse of dominant position by one undertaking
- ▶ Article 101 (3) TFEU gives a possibility of exemption

DEFINITIONS



- ▶ **Undertakings:** covers any entity* engaged in an economic activity, regardless of its legal status and the way in which it is financed.
- ▶ **Economic activity:** Any activity consisting in offering goods or services on a given market.
- ▶ **Anticompetitive Agreements:** those that confer an adverse effect on competition
- ▶ **Dominant position:** a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.

*individual

APPLICATION- TTBER



- ▶ **TT agreement:** patent, know-how license agreement, copyright including software or mixed patent, know-how or copyright license for the production of contract products, such
 - ▶ License Agreement (LA)
 - ▶ Material/Data Transfer Agreement (MTA), essentially a license
 - ▶ Technical Assistance Agreement (TAA)
- ▶ **Does not apply to**
 - ▶ pools agreements and licensing out from technology pools generally not covered by the TTBER **BUT** certain TT Guidelines
 - ▶ Distribution agreements, which may fall under VBER
 - ▶ R&D agreement, which may fall under the R&DBER

EXCEPTIONS: TTBER TIL 2026, CURRENTLY UNDER REVIEW



- ▶ Technology Transfer Block Exemption Regulation (TTBER) applies to agreements concerning “technology rights”
 - ▶ Creates a safe harbour
 - ▶ Lists hardcore restrictions
 - ▶ Contains a list of excluded restrictions
- ▶ Agreements that fall outside the TTBER, may not necessarily be illegal

SAFE HARBOR



- ▶ Consideration on **economic effects approach** to evaluate agreements rather than focusing solely on legal form
- ▶ TTBER provides a safe harbor for all technology transfer agreements within its scope, **safe harbor must be analyzed:**
 1. Determining if the parties to the agreement are competitors
 2. Assessing the market shares attributed to each party
 3. Examining whether the agreement contains any problem clauses e.g. hardcore or excluded restrictions

SAFE HARBOR



How do we determine competitors and market share?

- Are the parties competing undertakings or non-competing undertakings on product –geographic/technology markets?
- Does either party have more than 30% share on product - geographic / technology markets?

Outcome

- ▶ **Competing undertakings:** these agreements are exempt to the extent that the combined market share of the parties does not exceed **20%** on the relevant market(s)
- ▶ **Non-competing undertakings:** these agreements are exempt to the extent that the market share of each of the parties does not exceed **30%** on the relevant market(s)

HARDCORE RESTRICTIONS COMPETITORS



- ▶ Price fixing or other limitations on a party's ability to determine its prices when selling to third parties
- ▶ Output limitations, which restrict the quantity a party can produce and/or sell
- ▶ Market or customer allocations
- ▶ Restrictions on exploiting technology, including limitations on the licensee's ability to exploit its own technology or restrictions on research and development activities

HARD CORE RESTRICTIONS NON COMPETITORS



- ▶ Price fixing: agreements between non-competitors may impose a maximum or recommended price,
- ▶ Restrictions on passive sales related to territory or customers, with some exceptions,
- ▶ Restrictions on active or passive sales to end-users by licensees who are members of a selective distribution system operating at the retail level,

EXCLUDED RESTRICTIONS



- ▶ **Exclusive grant-backs by the licensee:** a requirement for the licensee to assign or **exclusively** license back any of its own improvements or new applications of the licensed technology.
- ▶ **No challenge clauses:** Exclusive license: NO challenge the validity of the licensor's intellectual property rights (IPRs) or, Non-Exclusive licenses: licensor to terminate the agreement if a challenge is made.
- ▶ **Restrictions on exploiting technology:** limitations on the licensee's ability to exploit its own technology or restrictions on either party's ability to carry out research and development.
(Hard Core/Exclusive but Excluded Restriction/non Exclusive)

CONSEQUENCES



- ▶ The presence of a **hardcore** restriction removes the benefit of the TTBER for the entire agreement
- ▶ An **excluded** restriction is not covered by the TTBER, but rest of the agreement remains covered IF severable
- ▶ Still, **Individual assessment** to define if despite of no under TTBER a competitive effect can be proven to be compliant
- ▶ **If the Agreement is assessed as not compliant:**
 - ▶ Fines by competition authorities
 - ▶ Nullity of the anticompetitive clauses / the agreement
 - ▶ Damages

EXCEPTION – R&DBER JULY 2023 NEW BER



- ▶ **Applicability of the R&DBER**
- ▶ Research and Development Agreement Block Exemption Regulation (R&DBER) applies to agreements concerning “R&D of products or technologies” and/or “Joint Exploitation of results out of R&D”
- ▶ R&D likely to promote technical and economic progress
- ▶ Joint Exploitation shall be related to product/services for which use of the results of R&D is indispensable
- ▶ Only when at least 3 other R&D efforts exist, was in the proposal but did not make it to the final version which facilitates application.

DEFINITION



R&D Agreement: activities aimed at acquiring know-how relating to products, technologies or processes, the carrying out of theoretical analysis, systematic study or experimentation, including experimental or demonstrator production, technical testing or products or processes =, the establishment of the necessary facilities up to demonstrator scale and the obtaining of intellectual property rights for the results

Joint Exploitation Agreement: joint exploitation of results of the R&D of contract products or contract technologies carried out of **a prior** R&D agreement

CRITERIA



Duration of the exception is depending of

▶ **Competing undertakings:**

- ▶ R&D term, provided that the combined market share does not exceed **25%**
- ▶ Joint Exploitation: Survival of the exception **7 years** following market insertion, provide that at the time of the agreement the market threshold has been met – no more than- **25%** on the relevant market(s)

Calculation based on data of preceding callendar year, if the +25% then duration is limited to 2 consecutives years following exceeding the treshold

CRITERIA



Duration of the exception is depending of

▶ Non-competing undertakings:

- ▶ R&D duration
- ▶ Beyond **7 years following market insertion** are long as combined market share does not exceed **25%**

Calculation based on data of preceding calendar year, if the +25% then duration is limited to 2 consecutive years following exceeding the threshold

R&D PROVISIONS



- ▶ Results shall be available to the parties for further R&D
- ▶ Exploitation rights to results may be limited
- ▶ Contributions may not be equal, however to balance such unequal contribution Parties may agree to compensation to access of results even for R&D.
- ▶ Compensation for access to results shall not be exaggerated and shall be reasonable oppose to prohibiting access
- ▶ Reasonable access to Background IP needed to exploit results

NON ACCEPTABLE PROVISIONS



- ▶ Restrictions on output
 - ▶ Market share
 - ▶ Limitations on production
- ▶ Excessive consideration for further access

In case exception does not apply under the R&D the agreement shall be assessed individually to define compliance.

THANK YOU



Carmen E. Correa M.

- ▶ c.correamartin@erasmusmc
- ▶ carmen@legal-dna.nl