CPR
International Institute for
Conflict Prevention & Resolution

2023

Mitigating Risk in Life Sciences Transactions

A Manual Written by the CPR Healthcare and Life Sciences Committee

Generously printed by

Fox Rothschild LLP
ATTORNEYS AT LAW

CPR Manual for Mitigating Risk in Life Sciences Transactions

Connie A. Matteo
David H. Colvin
Co-Chairs, Task Force on Mitigating Risk in Life Sciences Transactions

The CPR Manual for Mitigating Risk in Life Sciences Transactions is intended to be a guide only. The information contained in this publication should not be construed as legal advice or opinion, or a substitute for advice of counsel. The information contained in this publication is subject to change.

30 E. 33rd Street, 6th Floor
New York, NY 10016

www.cpradr.org

TABLE OF CONTENTS

Introduction and Overview

The Healthcare & Life Sciences ("HLS") Committee of the International Institute for Conflict Prevention and Resolution ("CPR") proudly presents this manual to aid legal practitioners with drafting life sciences transactions while identifying, allocating and mitigating risks in order to optimize the value of those transactions for the parties on either side of a deal (the "Manual").

This Manual is the product of a nearly two-year-long project undertaken by a dedicated and talented group of more than twenty-five (25) in-house and outside attorneys who have been on the frontlines of life science transactions. Under the leadership of CPR's HLS Committee, the Task Force on Mitigating Risk in Life Sciences Transactions (the "MRLST Task Force") was formed. It is part of the broader work that CPR is undertaking to promote dispute prevention in business relationships.

The purpose of the MRLST Task Force was to develop a resource to assist Licensors and Licensees (and their counsel) when they negotiate and draft long-term license and collaboration agreements in the healthcare and life sciences space. This Manual is intended to help minimize the risk of disruption to the business arrangement and prevent disputes so the parties can focus on maximizing value over the course of their business relationship. To achieve that objective, the MRLST Task Force identified the provisions most commonly found *and* zealously negotiated in healthcare and life sciences license agreements.

The following provisions are covered in this Manual:

I. Product
II. Exclusivity
III. First Commercial Sale
IV. Net Sales
V. Commercially Reasonable Efforts
VI. Representations and Warranties
VII. Technology Transfer
VIII. Audit Rights
IX. Recall
X. Change in Control
XI. Term
XII. Termination
XIII. Indemnification
XIV. Dispute Prevention & Resolution

The provisions were assigned as different chapters to different members of the Task Force. The author(s) of the chapters for each provision were then asked, in outline format, to: (i) describe and clarify the purpose and intention of each of the provisions; (ii) identify relevant legal and business considerations for deploying those provisions from the perspective of both the Licensor and Licensee; and (iii) offer the reader sample provisions.[1] The intent was to provide greater clarity to the provisions so that parties might enter the provisions with a better understanding as to how they can be utilized to best support the transaction. Throughout, the reader will note a discussion of how the provisions might be utilized in different circumstances with a recurring theme of assigning accountability to the party in the best position to exercise it.

This undertaking was truly a team exercise. On a monthly basis, and as drafting assignments were completed, the MRLST Task Force convened as a whole to review and analyze the work product generated by the authors. With the benefit of the expertise and thoughtful input of the members of the MRLST Task Force, each provision was subsequently revised, refined and finalized for publication in this Manual.

A word of caution: the reader should avoid blindly relying upon the sample provisions included in this Manual or recycling similar provisions from another agreement without carefully considering the impact of such provisions on the transaction, program, and parties.

[1] This Manual does not purport to cover or address every conceivable legal or business consideration. Nor are the sample provisions provided at the end of every chapter intended to apply to every licensing agreement or deal. Because the terms of every licensing agreement are specific to that particular agreement, the reader is strongly encouraged to use this Manual as a resource only and to seek appropriate advice and guidance that is tailored to the specific facts and circumstances of each agreement and transaction.

A final thought. The purpose of this Manual is not to provide either side of a licensing transaction – that is, the Licensor or the Licensee – with the tools to "win" the "battle" of contract negotiations. However, whether the Manual is used to serve each party or the transaction will ultimately be defined by the parties in each transaction. It is our hope that the Manual helps the parties ensure that it is the commercial transaction itself that is the "winner."

Connie A. Matteo
David H. Colvin
Co-Chairs, Task Force on Mitigating Risk in Life Sciences Transactions

About CPR

What We Do

Established in 1977, CPR is an independent nonprofit organization that promotes the prevention and resolution of conflict to better enable the pursuit of purpose through the CPR Institute and its subsidiary, CPR Dispute Resolution Services, LLC.

The CPR Institute builds capacity for dispute prevention and resolution through the thought leadership of its diverse members – companies, leading mediators and arbitrators, law firms, individual practitioners, and academics – who share best practices and develop innovative tools for dispute management through Committees and events.

CPR Dispute Resolution Services, LLC (DRS) is a subsidiary of CPR (also referred to herein as the CPR Institute). It is a boutique-style provider of leading-edge dispute management services – mediation, arbitration, custom appointing services, a panel of dispute prevention specialists, and more - that leverages resources generated by the CPR Institute. The DRS case administrators have legal degrees, a combined 50 years of experience in ADR, and speak five languages. The Panel of Distinguished Neutrals (the Panel or the Neutrals) is a carefully curated, diverse group of prominent, experienced subject matter and ADR experts based in 35 countries.

CPR's Rules & Procedures

Healthcare & Life Sciences disputes span a wide range of specialized and often highly technical issues. Parties with these types of disputes will benefit from a specialized neutral with understanding of the subject matter, thereby saving the time and cost in educating the neutral as to key issues relevant to their dispute.

Our rules, protocols, and model clauses are driven and informed by the CPR Institute, a collection of expert end-users on the front lines of dispute resolution. Parties can use any of CPR's Rules or Procedures to effectively manage their healthcare and life sciences disputes, including CPR's Administered Arbitration Rules or Mediation Procedures, any of CPR's Fast Track Procedures, or the Patent & Trade Secret Arbitration Rules for relevant disputes.

Healthcare & Life Sciences Panel of Neutrals

The Healthcare & Life Sciences Panel of Neutrals is comprised of highly qualified, diverse and experienced neutrals. They are experts in matters involving health care entities, hospitals and hospital systems, physicians and other providers, collaborative arrangements, managed care and HMOs,

pharmaceutical and medical device manufacturers, as well as the complex regulatory framework in which they operate. The panel also includes neutrals with experience in intellectual property related to health care and the life sciences, clinical trials, R&D and bioethics.

Healthcare and Life Sciences Committee

The Healthcare and Life Sciences Committee comprises leading practitioners, corporate counsel, academics, and neutrals with experience resolving disputes among healthcare and life sciences companies, institutions, and parties involving issues specific to these entities and the complex regulatory framework in which they operate. The Committee puts together seminars for the industry, convenes Task Forces to generate work product of relevance to the industry, and identifies and vets an industry-specific panel of neutral experts in Healthcare and Life Science-related disputes.

The Committee's Purpose is to develop and share best practices and resources for dispute prevention and resolution in the Healthcare and Life Sciences Industry.

CPR HLS Committee
MRLST Task Force Members[2]

Oliver J. Armas, Hogan Lovells
Preeti Bhagnani, White & Case
Arthur Cohn, DLA Piper
David H. Colvin (Co-Chair), Fox Rothschild
Diego Faleck, Faleck & Associados
Aaron R. Gardner, Arnold & Porter
Adam Golden, Freshfields Bruckhaus Deringer
Jade Harry, White & Case
Judith A. Hasko, Latham & Watkins
Erin Howell, Merck
Jeff Jay, Freshfields Bruckhaus Deringer
Winston S. Kirton, BakerHostetler
Christoph von Kupsch, Bayer AG
Mia Levi, Vice President, CPR Dispute Resolution
Mikael Linton-Wahlgren, Lindmark Welinder AB
Connie A. Matteo (Co-Chair), Pfizer
Maura K. Monaghan, Debevoise & Plimpton
Jenna Pellecchia, Sun Pharma
Thomas Rayski, Dechert
Luiz Ricardo de Oliveira Santos, Faleck & Associados
Peter H. Rosenbaum, Jenner & Block
Eric Rothman, Arnold & Porter
Lynn M. Russo, Hughes Hubbard & Reed
Paul Schneider, Pfizer
Erica Stein, Stein Arbitration
Alan Stevenson, Bayer Pharmaceuticals
Jonathan Wasserman, Hogan Lovells
Allen Waxman, President & CEO, CPR
Karen Wiswall, Freshfields Bruckhaus Deringer (*formerly*)
Samuel L. Zimmerman, Hogan Lovells

[2] The principal author(s) of each chapter are identified at the beginning of each chapter in the Manual.

Special thanks to the following team of editors who went above and beyond to review and edit the chapters and ready the Manual for publication: Preeti Bhagnani, Arthur Cohn, David Colvin, Jade Harry, Connie Matteo, Jenna Pellecchia, Erica Stein and Allen Waxman.

Additionally, thank you to Fox Rothschild LLP for its contributions to the design, editing and printing of the Manual.

I.

Product

Judith A. Hasko, Latham & Watkins
Christoph von Kupsch, Bayer AG

What Is the Purpose of Defining "Product"?

- A Product definition provision is intended to define – together with the definitions of "Field" and "Territory" – the *scope of rights* granted under a license, and/or – in a collaboration agreement – the products to be developed and/or commercialized under such collaboration.

- The Product definition is often also intended to limit the *licensed subject-matter*. This is typically the case when the licensed intellectual property – typically referred to as "Licensed Technology" or "Licensed IP" – is defined as all patents and know-how controlled by the Licensor that are covering Product(s) or – mainly in case of collaborations or early stage license deals – that are required (or useful) for development, manufacture and/or commercialization of Product(s).

- The Product definition typically has significant impact on the financial terms, as development or sales milestones and royalties are normally paid for Products.

- There are several variations of the defined term used more typically in life sciences agreements: Product, Licensed Product, Collaboration Product, etc. Our commentary below will apply to all of these defined terms generally, regardless of the defined term chosen for the specific agreement.

- The definition of Product also should reflect the type of product that is the focus of the agreement: therapeutic compounds, devices, methods or products discovered using a certain technology.

Relevant Considerations for Defining and Deploying "Product":

- The Product definition will limit the license scope and in turn, limit – in case of an exclusive license – the scope of enforcement rights and exclusivity under intellectual property licenses.

- As a matter of principle, Licensors will typically be interested in narrowly defining the product, whereas Licensees will want reasonable assurances that the scope of rights granted by the agreement provides enough flexibility to adjust development activities and product profiles for optimal commercial potential.

- Requirements for standing to enforce a licensed patent varies in each jurisdiction, but to enforce patent rights against competitors the Licensee may benefit from having a license under a broader set of products.

- If the product that is the subject of the agreement is known and identifiable:

    - The Licensor may (in case of an exclusive license) want to narrow the scope of the license to the existing product so it retains rights to exploit similar products, or variations thereof, independently of the Licensee. The Licensee may need rights to adjust or vary the product, including changing formulations, configurations, sequences or molecules to optimize the product profile, and may (in case of an exclusive license) want a product definition as broad as possible to ensure the Licensor will not create a similar product that could compete with the licensed Product in the market outside the scope of the licensed rights.

    - If the Licensor is not willing to accept a broad Product definition and the Licensee can accept a narrow scope of its use rights, but not a narrow scope of exclusivity, an alternative way to broaden the level of exclusivity may be achieved by agreeing upon an additional non-compete obligation of the Licensor, *i.e.* an obligation of the Licensor not to develop or commercialize a product with certain defined characteristics, for a certain period of time.[3] The leeway of such non-compete obligations is, however, limited for antitrust reasons, as such non-compete obligations can – contrary to a license with broad exclusivity – result in a situation where neither the Licensor nor the Licensee is allowed to exploit certain intellectual property of the Licensor in a certain area of use or in a certain manner. Antitrust requirements should in particular be considered with respect to the term of the non-compete obligation and the definition of the product characteristics. That being said,

[3] *See* Chapter on Exclusivity (Chapter II).

antitrust law should be taken into account not only when agreeing on non-compete obligations, but also with regard to the exclusivity of a license, particularly in a license agreement between (potentially) competing undertakings or if the exclusivity extends to areas where the parties expect that the Licensee will not make use of the license.

- If the product that is the subject of the agreement is yet to be identified or discovered as part of a collaborative effort:

    - Defining a product that does not yet exist is challenging. It is helpful to focus on the key attributes of the product the parties want to identify or discover. For example, are the parties focused on:

        - Products binding to a certain cellular target, whether a biologic or small molecule;

        - Biologic products that have a certain genetic or amino acid sequence;

        - Biologic products that are antibodies or variants thereof;

        - Cellular therapy products having certain genetic or amino acid sequence properties; or

        - Any and all products that modulate a specific target, regardless of modality?

    - Each party will want to make sure that the products resulting from collaborative efforts are made available for development and commercialization in accordance with agreed business terms. One question is whether the exact end product identified or discovered collaboratively is defined as the Product, or whether derivatives, variants or other molecular forms of that product, such as interim collaboration results, are also to be treated as the licensed Product.

    - In this context, each party will want to make sure that products independently developed outside of the collaboration are not encumbered by obligations to the other party. For this reason, broad Product definitions that are not limited to one (or few) specified development candidates but also include variations of the Product can

include a limitation of the Product definition to those products that are covered by a valid claim of a Licensed Patent or at least generated with the use of Licensed Know-How (which may include certain know-how generated within the collaboration). In the latter case, to address the increased "contamination" risk with respect to know-how disclosed or generated within the collaboration, the Licensee may also wish to exclude certain types of general know-how from the definition of "Licensed Know-How" (triggering a cost-bearing Product) and to instead arrange for a – potentially mutual – additional non-exclusive, cost-free "anti-contamination" license under such general know-how for any purpose.

- Specific issues around the impact of the Product definition on financial obligations of the Licensee:

    - In case of a Product definition that extends to derivative products generated by the Licensee, Licensees may wish to reduce the license fees for such derivative products created by or on behalf of themselves based on the Licensor's product or technology, as opposed to the fees to be paid for development and commercialization of precisely the development candidate provided by the Licensor. In this case, the agreement should differentiate between various sub-types of Product, such as Licensor Products and Derivative Products, with different financial obligations attached to them.

    - Under certain conditions, Licensors may want to describe the Product more broadly in the sense that no use of licensed intellectual property is required to trigger the payment obligations. From the Licensor's perspective, such a clause could be desirable in case of any concerns that the Licensee could benefit from the Licensed Technology even though a use of the Licensed Technology cannot be proven. From the Licensee's perspective, such a clause can, however, pose a significant threat and potential scenarios should be carefully considered before, in very exceptional scenarios, potentially accepting such a wording. Such a payment obligation in the absence of any demonstrated use of Licensed Technology can also trigger significant antitrust issues.

    - When milestones become due on a "Product-by-Product" basis (*e.g.* for having reached a certain development stage, such as start of Phase 1, Phase 2 or Phase 3 clinical trials) or

incremental royalties rates are agreed on a "Product-by-Product" basis (*i.e.* for each Product, the royalty rate increases for the portion of net sales that exceeds a certain threshold amount), the parties may need to address the issue of how to differentiate one Product from another Product - *i.e.* what deviations result in a new Product as opposed to a variation of the Product that has already achieved the milestone. Here a broad definition of one "Product," as opposed to another one (*i.e.* variations not resulting in a new Product), would benefit:

- the Licensee, with respect to milestones paid on "Product-by-Product" basis; and

- the Licensor, with respect to an incremental royalty rate.

- For software or devices, the product may be defined by reference to certain versions of the software or the device that exist as of the effective date of the license, with separate terms defining access to future versions, but for therapeutic compounds, there may be more flexibility allowed if the Licensee may improve or modify the therapeutic compound under the terms thereof.

Sample Definitions of "Product":

- "Collaboration Product" means (a) a product that includes a [Development Compound], or (b) any [biologic] [therapeutic] [pharmaceutical] product that contains a [variant] [derivative] [other chemical form of] the product described in (a) that is made by or on behalf of Licensee, its Affiliates or sublicensees in the course of [performing activities under this Agreement] [conducting the Collaboration] [exercising its license rights under this Agreement].

- "Product" means any product that includes or incorporates a [Compound], in any and all dosage forms and formulations [and that is covered by at least one Valid Claim of a Licensed Patent [or [directly] generated with the use of Licensed Know-How].

- "Licensed Product" means any product, service and/or process which constitutes, utilizes, incorporates or is based on the [Licensed Technology].

- "Product" means collectively the [Formulated Compound] and the [Applicator Device].

- "Licensed Product" means a product or part of a product or service:

    - (A) the making, using, importing or selling of which, absent this license, infringes, induces infringement, or contributes to infringement of a [Valid Claim] of a Licensed Patent; or

    - (B) which is made with uses or incorporates any method covered by a [Valid Claim] of a Licensed Patent; or

    - (C) which is made with, uses or incorporates any [Technology] [Licensed Know-How][; or

    - (D) specifically binds to or directly modulates [a molecule] listed in Appendix X].

  Please note that example (D) of the above definition of "Licensed Product" could – in case it is a realistic scenario that licensee could independently develop a product that binds or modulates the listed molecule – result in milestone and royalty obligations without actual use of any licensed intellectual property.

CPR
International Institute for
Conflict Prevention & Resolution

Generously printed by

Fox Rothschild LLP
ATTORNEYS AT LAW