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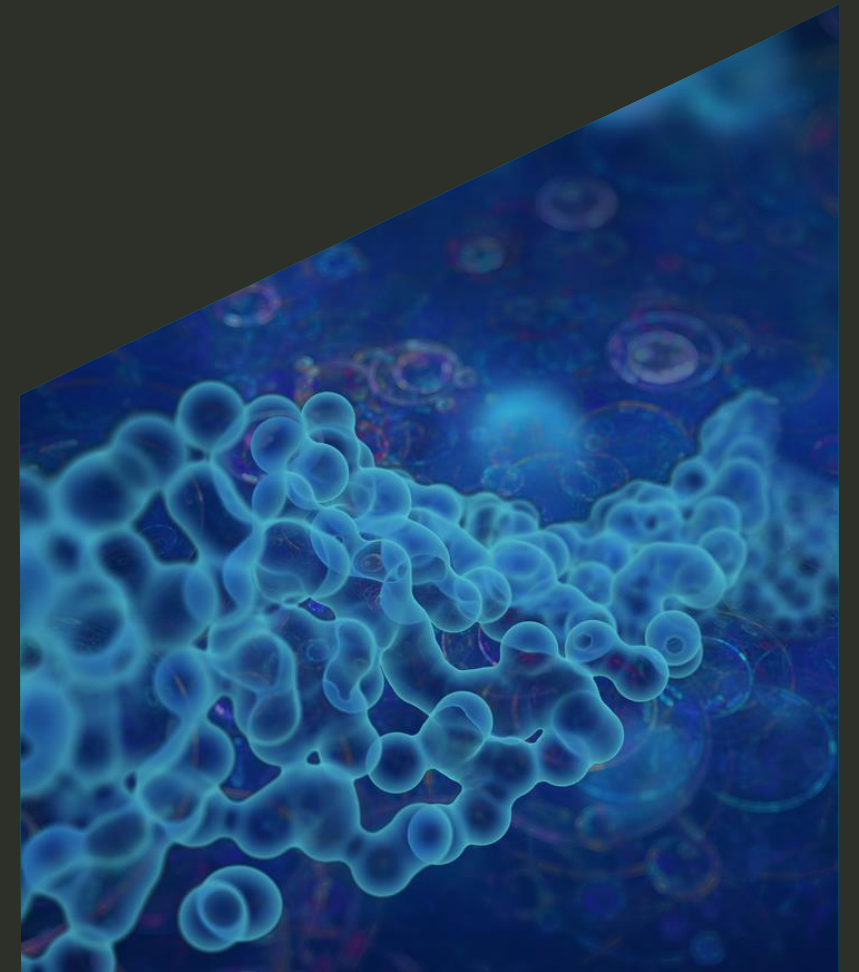
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LICENSING : AN INTERNATIONAL PERSPECTIVE

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OUTLINE

- Responsibility for development and regulatory activities
- Manufacture and supply
- Ownership and access to improvements
- Enforcement of patent rights
- Withholding tax
- Term and consequences of termination
- Dispute resolution
- Applicable law



WHY PARTNER INTERNATIONALLY?

- Partner
 - Benefit of a partner with resources and knowledge to develop and commercialize a product in jurisdictions where licensor lacks such resources and knowledge
- Cash
 - Raise cash that does not dilute ownership
 - Monetize an asset which is not the primary focus for licensor or which the licensor does not plan to develop in a particular field/indication or territory
- Cross-licensing

RESPONSIBILITY FOR DEVELOPMENT AND REGULATORY ACTIVITIES

The Role of the Joint Steering Committee (JSC)

- Global oversight and coordination
- Global Development Plan
 - Integrate global and local clinical trials
 - Assigning responsibilities
 - Regulatory data sharing and cooperation
 - Which party holds approvals

RESPONSIBILITY FOR DEVELOPMENT AND REGULATORY ACTIVITIES

(...But really, who has the final say?)

- Final decision-making authority
 - Division of final says among the parties
- Dispute resolution

RESPONSIBILITY FOR DEVELOPMENT AND REGULATORY ACTIVITIES

- Global Commercialization Plan
 - TM usage
 - Coordinated marketing messaging
 - Overall commercial strategy
- Pharmacovigilance
 - Sharing of safety data and regulatory reporting
 - Global Safety Database is typically owned by Licensor

MANUFACTURE AND SUPPLY

- One party usually controls manufacturing technology
- Supply of clinical development products
- Supply of commercial products
- Sharing of CMO resources
- Technology transfer for local manufacturing
- Technology transfer for second sourcing

MANUFACTURE AND SUPPLY

US patent law considerations

- ✓ Before entering into a supply agreement, check with your US patent attorney.
- A supply agreement can constitute a “sale” and can destroy the novelty of your US patent application.



MANUFACTURE AND SUPPLY

US patent law considerations – let's take a closer look



- America Invents Act (AIA) moved the US to a first-to-file (as opposed to first-to-invent system) and greatly *expanded the definition of prior art* and introduced the use of post grant review.
 - Before the AIA: Sec. 102(b) of the US Patent act barred patentability of an invention that was “...on sale in this country, more than one year prior to the date of the application for patent.”
 - After AIA: Sec. 102 bars patentability of an invention that was “on sale, *or otherwise available to the public* before the effective filing date of the claimed invention.” 35 USC Sec 102(a)(1).

MANUFACTURE AND SUPPLY

US patent law considerations – let's take a closer look

- *Helsinn Healthcare v. Teva Pharm. USA, Inc.* (2019).
 - Helsinn developed a drug to treat chemotherapy-induced nausea and vomiting.
 - Early 2000's: Phase III clinical trials to study a 0.25 mg and a 0.75 mg dose of the drug; Helsinn entered into a license agreement and supply agreement with MGI Pharma.
 - Jan. 2003 (2 yrs after the supply agreement): Helsinn filed a provisional patent application covering a 0.25 mg dose of the drug.
 - Over the next 10 years, 4 patent applications that claimed priority to the Jan. 2003 application (3 of 4 were pre-AIA; 1 after AIA came into effect).

MANUFACTURE AND SUPPLY

US patent law considerations – let's take a closer look

- Helsinn sued Teva for patent infringement.
- Teva counterclaimed that the patents were invalid under the on-sale bar.
- The outcome: All the patents were held to be invalid, including, ultimately, the post-AIA application.

MANUFACTURE AND SUPPLY

US patent law considerations – what did the courts in *Helsinn* say?

- Federal Circuit: *“There can be no real dispute that an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community would understand that term.”*
- Supreme Court: *“Because we determine that Congress did not alter the meaning of “on sale” when it enacted the AIA, we hold that an inventor’s sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under §102(a).”*

MANUFACTURE AND SUPPLY

- Bayh-Dole Act:
 - Requires that products developed with federal funds and used and sold in the US, be substantially manufactured in the US.
 - In granting exclusive rights to use or sell any subject invention in the United States, ensure that each agreement requires that any products embodying the subject invention will be manufactured substantially in the United States.
 - A request for waiver may be considered by the NIH.

OWNERSHIP OF IMPROVEMENTS

- Ownership by inventorship vs. joint ownership of all improvements
 - Determination of inventorship with reference to US law
- ✓ Regardless, state consequence of joint ownership as rules differ across jurisdictions.
- An example to illustrate the point:

OWNERSHIP OF IMPROVEMENTS

Example: US

- *In absence of agreement to the contrary, **each joint owner** of a patent **may** make, use, offer to sell, sell and import the patented invention without the consent of the other joint owners and **without accounting** to the other joint owners for any share of the profits.*
- Each co-owner can grant non-exclusive licenses without consent of the co-owner.
- Co-owners **must join** in a suit for infringement. Thus, absent some agreement to the contrary, **each co-owner of a patent can effectively block the other co-owner(s) from bringing infringement suits.**

OWNERSHIP OF IMPROVEMENTS

Example: France

- *In the absence of an agreement to the contrary*, a co-owner can **exploit** the patent but **must share the revenues** with other co-owners that do not exploit the patent and that have not granted a license to a third party to exploit the patent.
- Each co-owner can **grant a non-exclusive license** but must **share the revenues** with the other co-owners that do not exploit the patent and that have not granted a license to a third party to exploit the patent.
- Each co-owner **can bring a patent infringement** action provided it notifies the others.

ACCESS TO IMPROVEMENTS

- ✓ Licensee may want that the improvements be included in the license
 - In the Field and in the Territory
 - (will it extend the royalty term? royalty discount for weaker patents?)
- ✓ Licensor may wish that Licensee grant Licensor (and its sublicensees) a license to Licensee improvements:
 - Outside the Territory, and
 - Outside the Field.

ENFORCEMENT OF PATENT RIGHTS

- Party having responsibility for a territory typically has the first right to enforce in that territory
- Control of litigation when technology is used in multiple fields or territories
 - The issue: litigation puts the patent in jeopardy
 - Problem of platform technology; many licensees
- Right of licensees and co-owners to sue for infringement vary across jurisdictions, regardless of what the agreement says.
- An example:

ENFORCEMENT OF PATENT RIGHTS

Example

- Typical infringement clause:

“The Licensee shall have the first right, but not the obligation, to enforce any Licensed Patents in the Field in the Territory.”

- Can a licensee sue for infringement on its own if the license gives the licensee that right?

ENFORCEMENT OF PATENT RIGHTS

- **US:** It depends.
 - “[A]n exclusive licensee that does not have ‘all substantial rights’ to a patent must *join the patentee to bring suit*”. *Luminara Worldwide, LLC. V. Liown Elecs. Co.* (Fed. Cir. Feb. 29, 2016).
- ✓ Licensee would want that the license agreement require the owner(s) of the patent to join any infringement action brought by the licensee.

ENFORCEMENT OF PATENT RIGHTS

- **France:** Yes, an exclusive (and non-exclusive) licensee can sue for infringement if the license agreement authorizes it.
 - *“Unless otherwise stipulated in the license agreement, [the infringement action] is also available to an exclusive licensee on condition that, [...the exclusive licensee] informs the owner.”*
 - *“The holder of a non-exclusive license may bring an action for infringement, if the license contract expressly authorizes him to do so, on condition that [...the non-exclusive licensee] informs the owner.”*

Code of Intellectual Property, L615-2.

WITHHOLDING TAX

- Royalties or other payments may be subject to withholding taxes
- Two approaches:
 - Licensee pays tax, subtract from royalty payment, provide tax documentation to licensor
- Licensee pays tax, no subtraction from royalty payment (gross up), pay back licensee if tax recovered by licensor

TERM

- Typically, the license expires, on a country-by-country basis, on the later of: (i) X years after the First Commercial Sale of the Licensed Product in such country and (ii) the last to expire Valid Claim of a Licensed Patent in such country.
- Consider also, (iii) the expiration of regulatory exclusivity and (iv) generic competition.

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WHAT DOES HE HAVE TO DO WITH PATENT LICENSING?



TERM AND POST-EXPIRATION ROYALTIES

- US Supreme Court: Post-expiration royalties constitute **patent misuse** in US
 - *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).
 - *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1979).
 - *Kimble v. Marvel Entertainment, LLC*, 576 U.S. 446 (2015).
 - ✓ Step-down royalties for K-H and other business arrangements are OK; no clear guidance on the % of the step-down; this is a US issue (so not applicable if your Territory is Japan).

CONSEQUENCES OF TERMINATION

- ✓ Ensure that licensor has the ability to continue to develop and commercialize the product (unless licensor is at fault).
 - License from licensee to licensor of regulatory approvals, TM, improvements, know-how, etc.
 - Consider the financial conditions of the license back to licensor
- ✓ As licensee, ensure that the sublicenses will survive termination of the head license.

DISPUTE RESOLUTION

- JSC
- Escalation to officers
- Arbitration vs Litigation
 - Seat of arbitration/jurisdiction
 - Confidentiality/publicity
 - Convenience/speed
 - Cost
 - Appeal
- Discovery and burden of proof (e.g., CRE)

CHOICE OF LAW

- Impacts interpretation of key clauses
 - Exclusivity
 - CRE
 - Good faith efforts to agree
 - Liability
 - Implied terms
 - Most US agreements subject to New York and Delaware

THANK YOU
QUESTIONS?

