

AUTM Annual Meeting 2018

Sublicence Income Sharing

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What is a Sublicense?

- ❑ First step is to clearly define the rights granted:
 - ❑ Sublicense should be defined as “**any right**” granted to third parties under the license grant, and capture all types of agreements including options, bundled IP rights, profit-sharing agreements etc.
- ❑ Questions for TLO to ask:
 - ❑ Is the licensee intending to “flip” the license?
 - ❑ Will sublicensing be the sole method of revenue generation?
 - ❑ Will the licensee be bundling University IP and it's own IP in agreements with third parties?
 - ❑ E.g. Licensee licenses it's proprietary platform, plus options university product-related IP

Sublicense Income Sharing

- ❑ A very difficult issue
 - ❑ Need to anticipate an event that won't happen until well into the future
 - ❑ Negotiators won't know:
 - ❑ The value of the technology at the time of the sublicense
 - ❑ How much the licensee will have invested in developing the technology by the time of the sublicense
 - ❑ The bargaining strengths of the licensee and sublicensee
 - ❑ What the financial structure of the sublicense will be
- ❑ University's main objective will be to ensure that the licensee can't structure the sublicense to minimize what it pays the university

Solution

- ❑ University gets a piece of every payment that the licensee gets from the sublicensee

“You will pay me every which way there is”

Louis P. Berneman

- ❑ Exclusions for items for which there is a deliverable, and are documented in itemized accounts :
 - ❑ Patent expense reimbursement
 - ❑ Research support payments
 - ❑ Purchases of equity

Solution

❑ Three models:

1. Pass Through

- ❑ University gets same running royalty on sublicensee's sales, as if the licensee sold the product; plus
- ❑ A set percentage of every payment received other than running royalties (sometimes termed “non-royalty income”)

2. Allocation

- ❑ University gets a set % of every payment the licensee gets from the sublicensee
 - ❑ Including running royalties

3. Tiered Allocation

- ❑ University gets a lower % of payments received from sublicensee, before commercialization
- ❑ University gets a higher % of running royalties after commercialization
- ❑ Tiers may be based on timing of sub-licensing (flipping) post-license execution (e.g. year 1-25%, Year 2-20%, year 3-15%)

A Standard Sublicense Income Definition (Pass Through)

- ❑ “Sublicense Income” means payments or other value that Company receives from a Sublicensee in consideration of a Sublicense granted by Company, including without limitation, license fees, equity, milestone payments, license maintenance fees, payments for distribution rights, and the fair-market value of any non-cash consideration, but excluding the following payments:
 - (a) payments made in consideration for the issuance of equity or debt securities of Company at fair market value,
 - (b) payments specifically committed to and incurred in the research and development of Licensed Products, including patent-related costs and expenses, and
 - (c) running royalties.

What Percentage?

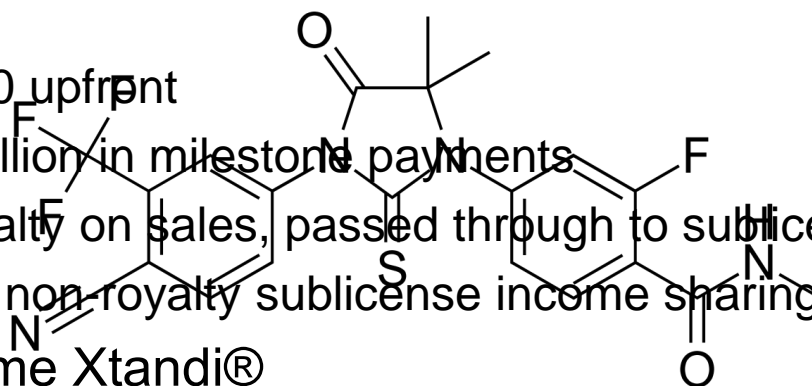
- ❑ 25% Rule a good starting point
- ❑ Some agreements step down the % as licensee adds more value to the university's IP. Tiers may be tied to due diligence Milestones:
 - ❑ Up to Phase 1 Entry 25%
 - ❑ Up to Phase 3 entry 20%
 - ❑ After Phase 3 entry 10%
- ❑ Additional pressure to lower percentage for start-ups, if university owns equity
 - ❑ Lets licensee use sublicense payments for corporate development
 - ❑ Reduces company's need to raise capital
 - ❑ Reduces dilution of university's ownership
 - ❑ Negatives include risk, a longer wait for university to share in the upside, and possibly reduced revenue

Related Best Practices

- ❑ Ensure in your license that TLO gets an *un-redacted* copy of every sub-license
- ❑ Compare the “*net sales*” definitions in sub-licence to that in your license
 - ❑ Large companies may prescribe their definition to a startup
- ❑ Retain the additional right to *audit* income reports

Regents of the University of California vs. Medivation

- ❑ Medivation licensed ~170 diarylthiohydantoin compounds from UCLA in 2005
 - ❑ The RD Series
 - ❑ Bind and inhibit the androgen receptor
 - ❑ Preclinical
 - ❑ \$15,000 upfront
 - ❑ \$2.8 million in milestone payments
 - ❑ 4% royalty on sales, passed through to sublicensees
 - ❑ 10% of non-royalty sublicense income sharing
- ❑ RD162' became Xtandi®
 - ❑ Best drug for advanced prostate cancer
 - ❑ 2016 sales ~\$2.2 billion



Regents of the University of California vs. Medivation

- ❑ In 2009, Medivation did a deal with Astellas
 - ❑ Drug just entering Phase 3
 - ❑ \$110 million upfront
 - ❑ \$335 million in milestone payments
 - ❑ \$320 million in sales milestone payments
 - ❑ 50 : 50 co-development and profit sharing in U.S.
 - ❑ Running royalties tiered from low teens to low twenties in RoW
- ❑ In March 2016, UCLA monetized its royalty rights for \$1.14 billion
 - ❑ Having already received ~\$300 million in running royalties and sublicense income sharing payments
- ❑ In August 2016, Pfizer acquired Medivation for \$14 billion

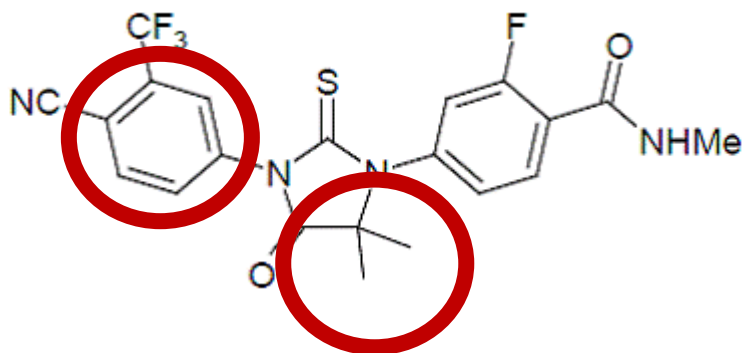
Regents of the University of California vs. Medivation

- ❑ In other words, as rip roaring a success for academic research and technology transfer as you could ever hope to see
- ❑ So, UCLA and Medivation love each other like brothers, right?
- ❑ Wrong
 - ❑ 3 rounds of litigation
 - ❑ First round was about two compounds that UCLA contended weren't licensed to Medivation
 - ❑ The A-series
 - ❑ Differed from the RD-series by replacement of a benzene ring by a pyridine ring
 - ❑ One of the compounds was the A series analogue of RD162 the precursor to Xtandi®

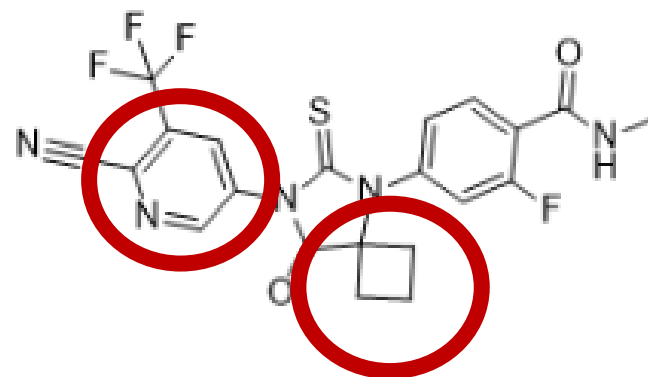
Regents of the University of California vs. Medivation

Disclosure: I assisted Medivation / Pfizer in the third round of litigation between these two parties. This presentation only draws on publicly available information.

An article going into more depth on the issues discussed herein will appear in the March issue of *les Nouvelles*



Xtandi®



Apalutamide

Regents of the University of California vs. Medivation

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- ❑ Wrong
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 - ❑ The A-series
 - ❑ Differed from the RD-series by replacement of a benzene ring by a pyridine ring
 - ❑ One of the compounds was the A series analogue of the precursor to Xtandi
- ❑ Judge Munter ruled that Medivation only had rights to the RD series

Regents of the University of California vs. Medivation

- ❑ UCLA licensed A-series to Farallon Biosciences, founded by Sawyers and Jung
 - ❑ Farallon became Aragon
 - ❑ Acquired by J&J in 2013
 - ❑ In Phase 2
 - ❑ \$650 million upfront
 - ❑ \$350 million in milestones
 - ❑ NDA submitted October 2017
 - ❑ Spun off Seragon before acquisition
 - ❑ Rights to some estrogen receptor compounds
 - ❑ Acquired by Genentech in 2014
 - ❑ \$725 million upfront
 - ❑ \$1 billion in milestone payments
 - ❑ Product failed

Regents of the University of California vs. Medivation

- ❑ Second and Third Disputes: Sublicense Income sharing
- ❑ UC uses a standard definition of Sublicense Income
 - Sublicensing Income includes income received including but not limited to license issue fees, milestone payments, and the like but specifically excludes royalties on the sale or distribution of Licensed Products or the practice of Licensed Methods
- ❑ Medivation argued that Sales Milestone payments are “royalties on the sale” and hence excluded

Regents of the University of California vs. Medivation

❑ Judge Munter disagreed:

The term "milestone payments" found in the above definition of Sublicensing Income is not defined in the [Agreement]. In the context of licensing agreements such as the [Agreement], the term "milestone payments" is commonly understood in the industry to mean event-driven or success payments, which are distinct from royalty payments. It is also commonly understood in the industry that the term includes payments made upon the occurrence of both regulatory milestones and sales milestones.

Each sales milestone payment is owed only once, and the maximum total payment owed to Medivation is \$320 million. Unlike sales milestones, royalties are triggered by individual sales, they are based only on sales outside of the U.S., and they are recurring.*

* Astellas deal included 50:50 co-development and profit sharing in U.S. and running royalties ex-US

Regents of the University of California vs. Medivation

- ❑ Awarded Regents 10% of \$320 million
 - ❑ \$32 million
- ❑ Appealed all the way to the Supreme Court of California
 - ❑ Upheld

Language

- ❑ The language that caused UC so much trouble:
 - ❑ Sublicensing Income includes income received including but not limited to license issue fees, **milestone payments, and the like** but specifically excludes royalties on the sale or distribution of Licensed Products or the practice of Licensed Methods.....

Language

- ❑ Suggested Improvements:
 - ❑ Sublicensing Income includes income received including but not limited to license issue fees, **milestone payments, including, but not limited to, payments conditional on the achievement of patent, pre-clinical, clinical, regulatory, sales or any other milestone** but specifically excludes royalties on the sale or distribution of Licensed Products or the practice of Licensed Methods.....

Language

- ❑ Other potential issues
 - ❑ License Maintenance Fees
 - ❑ Relatively uncommon in corporate collaborations
 - ❑ Include anyway
 - ❑ Annual Minimum Royalties
 - ❑ Again, relatively uncommon in corporate collaborations
 - ❑ Effectively a license maintenance fee
 - ❑ Include unless subsequently credited against running royalties

Regents of the University of California vs. Medivation

- ❑ Third Dispute
- ❑ Regents contended that Profit Sharing payments are not “royalties on the sale”
 - ❑ Therefore not excluded from Sublicensing Income
 - ❑ Therefore Regents should receive 10% of Medivation’s 50% Profit Share
 - ❑ In addition to the pass through running royalty of 4% of Astella’s Net Sales
 - ❑ Would have roughly doubled Regents’ revenues
- ❑ Case settled May 2017
 - ❑ Therefore no judicial resolution and determination

Are Profit Sharing Payments “Royalties on the Sale”?

- ❑ My 2¢ worth:
 - ❑ The original meaning of “royalty” was sharing profits with the Crown
 - ❑ The formula for a running royalty is:

$$\text{Running royalty} = \text{Royalty base} * \text{Royalty rate}$$
 - ❑ Profits are a perfectly acceptable royalty base
 - ❑ 50% is a perfectly acceptable royalty rate
 - ❑ Therefore 50% of Operating Profits is a perfectly acceptable running royalty
 - ❑ Medivation granted Astellas an exclusive, royalty-bearing sublicense
 - ❑ The profit sharing payments are Medivation’s only recurring payments from Astellas in the U.S.
 - ❑ Only thing that can be a running royalty
 - ❑ Medivation’s profit sharing payments in U.S. were ~2x the tiered running royalties in RoW as a % of Net Sales
 - ❑ The difference is Medivation’s return on the \$448 million it spent as its share of Xtandi®’s U.S. development costs after the Astellas deal

Language

- ❑ The second problem area:
 - ❑ Sublicensing Income includes income received including but not limited to license issue fees, milestone payments, and the like, including, but not limited to, payments conditional on the achievement of patent, pre-clinical, clinical, regulatory, sales or any other milestone but **specifically excludes royalties on the sale or distribution of Licensed Products or the practice of Licensed Methods.....**

Language

- ❑ Suggested improvements:
 - ❑ Sublicensing Income includes income received including but not limited to license issue fees, milestone payments, and the like, including, but not limited to, payments conditional on the achievement of patent, pre-clinical, clinical, regulatory, sales or any other milestone but **specifically excludes running royalty payments on the sale or distribution of Licensed Products or the practice of Licensed Methods, irrespective of whether based on sales revenues, unit sales or some measure of profits.....**

Language

- ❑ Other potential problem areas:
 - ❑ Research support
 - ❑ What if payments not based on time and expenses, but only paid on achievement of technical milestones
 - ❑ Shouldn't get sucked into milestone payments
 - ❑ Potential language:
 - ❑ ..excluding payments received for research carried out by licensee at request of sublicensee, whether made to reimburse scientific effort on an FTE plus expenses basis, or on achievement of scientific milestones

Language

- ❑ Other potential problem areas:
 - ❑ Purchases of Equity
 - ❑ Licensee could be tempted to sell shares at a big premium rather than selling at Fair Market Value and receiving a large upfront fee
 - ❑ In order to avoid paying a % of the upfront fee to the licensor
 - ❑ Solution:
 - ❑ Only allow sale at Fair Market Value
 - ❑ Or some defined premium to Fair Market Value
 - ❑ Say 20%
 - ❑ What's Fair Market Value?
 - ❑ If licensee is publicly traded:
 - ❑ Average closing price on the 10 trading days immediately prior to announcement of the transaction
 - ❑ If licensee is privately held:
 - ❑ Price per share of the most recent financing

Language -- Allocation

- ❑ These considerations apply equally to an allocation deal
 - ❑ Running royalty language would be in the “what’s included” wording
 - ❑ Could add “each and every payment received from a sublicensee” at the beginning