

Sublicense Income Sharing

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Sublicensing

- ❑ Right to sublicense always included with exclusive licenses
 - ❑ Licensors want the licensee to have the right to find an alternative use for the technology if they decide to stop developing it
 - ❑ (US) legal precedent indicates an exclusive licensee may have the right to sublicense even if not explicitly stated
- ❑ Usually not included in non-exclusive licenses
 - ❑ Since licensors still have rights to grant additional licenses, any interested party can get a license from them
 - ❑ Licensors would get the revenue from the new licensee directly
 - ❑ A very few non-exclusive licenses do include the right to sublicense
- ❑ So how does the income the licensee gets from the sublicense get divided up?
 - ❑ Often depends on the size of the licensee

Sublicense Income Sharing

- ❑ A really big deal
- ❑ Most technologies licensed to start-ups will be sublicensed before they reach the marketplace
 - ❑ “Partnered”
 - ❑ “Collaboration”
- ❑ Substantial value can be created
 - ❑ You see some very big numbers out there
 - ❑ “BioBucks”
 - ❑ The sum of all the lump sum payments if all the envisioned products happen and get approved in all markets and exceed all sales targets
- ❑ Particularly in life sciences, this may where the value will be realized
 - ❑ So, it’s one of the most important elements of the negotiations

Sublicense Income Sharing

- ❑ By the time it happens, the original deal doers will be long gone
 - ❑ Certainly on the corporate side
 - ❑ Along with all the goodwill
- ❑ Sublicense income sharing provisions will now be considered a “tax”
 - ❑ And who likes paying taxes?
 - ❑ And who leans over backwards to pay as much taxes as they can?

Sublicense Income Sharing

- ❑ Because sublicense income provision shifts value to the university from the original licensee, that licensee will want to try minimize sublicense income provisions.
- ❑ Licensee may try to treat payments received as falling outside definition of sublicense income.

Sublicense Income Sharing

- ❑ It's 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

The Incentive Problem

- ❑ The licensee has the incentive to:
 - ❑ Say the deal isn't a sublicense
 - ❑ The payments aren't related to the sublicense but to some other deal between licensee and sublicensee
 - ❑ Which just happened to be signed simultaneously!
 - ❑ The payments aren't within the definition of sublicense income
 - ❑ Minimize the percentages
- ❑ It's a dirty world out there

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 its own IP in agreements with third parties?
 - ❑ e.g. Licensee licenses its proprietary platform, plus options to university product-related IP

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 "sublicense income" or "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%)

Standard Sublicense Income Definitions (Pass Through)

- ❑ “Net Sales” means sales by Licensee, its Affiliates and any Sublicensee
- ❑ “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

What Running Royalty Rate?

- ❑ Highest I've seen passed through is 4%
- ❑ If Non-royalty Income sharing is 25%
 - ❑ Breakeven is 16% running royalty rate from sublicensee to licensee
 - ❑ $16\% * 0.25 = 4\%$

Related Best Practices

- ❑ Ensure in your license that TLO gets an *unredacted* copy of every sublicense
- ❑ Compare the “*Net Sales*” definitions in sublicense to that in the primary license
 - ❑ Large companies may prescribe their definition to a startup
- ❑ Retain the additional right to *audit* income reports

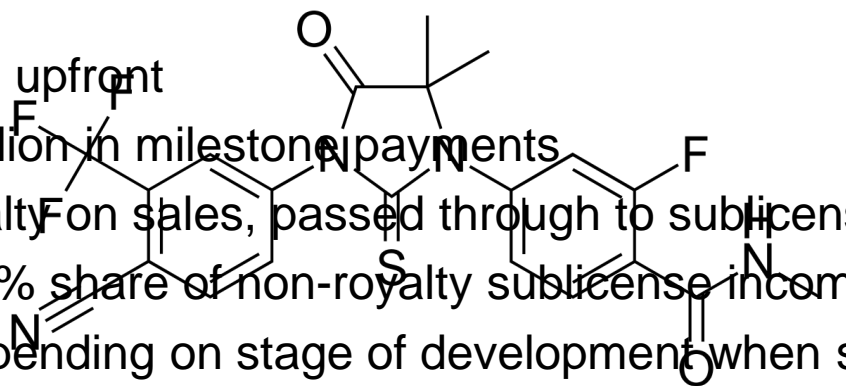
What If They Want to Reduce the Percentages Later?

- ❑ They argue that the deal also includes a lot of IP they've created themselves
 - ❑ That's why they're keeping all the money over the pass through running rate and the sublicense income sharing percentages
- ❑ They're going to have to share with another university as well
 - ❑ So?
 - ❑ Remember the licensing mantra
 - ❑ A deal's a deal

Case Study

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
 - ❑ 25%-10% share of non-royalty sublicense income
 - ❑ Depending on stage of development when sublicense done
- ❑ RD162' became Xtandi®
 - ❑ Best drug for advanced prostate cancer
 - ❑ 2019 sales ~\$4 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 development 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

Look at the Build Up in Value

❑ 2005	\$3 million
❑ 2009	\$775 million
❑ 2016	\$15.4 billion

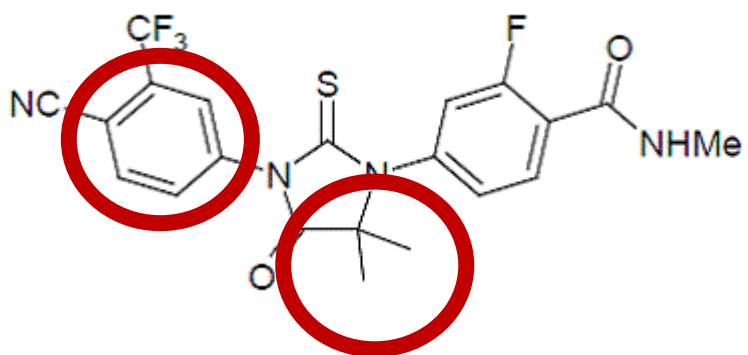
Regents of the University of California vs. Medivation

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

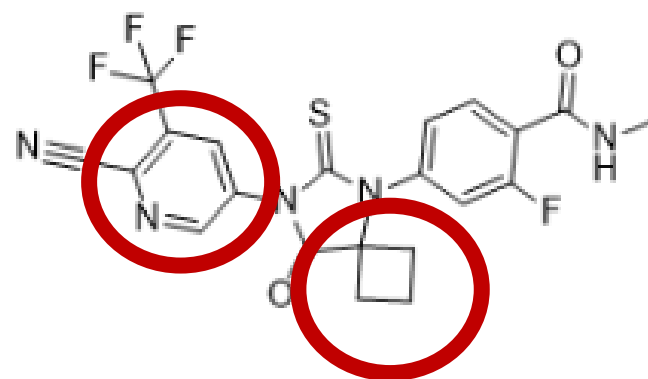
An article going into more depth on the issues discussed herein was the lead article in the March 2018 issue of *les Nouvelles*

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®



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

- ❑ Turned out to be a really big deal
 - ❑ 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
 - ❑ Approved February 2018
 - ❑ \$1.5 billion sales forecast for 2022
 - ❑ UCLA monetized royalty payments for \$104.5 million in Q1 2019

Regents of the University of California vs. Medivation

- ❑ But wait, there's more:
 - ❑ Farallon 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
- ❑ Deal was a dress rehearsal for J&J's \$30 billion acquisition of Actelion in January 2017
 - ❑ Spinout called Idorsia
 - ❑ J&J acquired rights to apocitinan from Idorsia in December 2017
 - ❑ €230 mm upfront
 - ❑ Running royalties of 20-35%

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 event** 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 the running royalty rate
 - ❑ And 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.
 - ❑ Therefore, the 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 try to sell shares at a big premium rather than receiving an upfront fee and selling at Fair Market Value
 - ❑ 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
 - ❑ Net Sales definition would be:

“Net Sales” means sales by Licensee and its Affiliates
 - ❑ Sublicense Income definition would be:

“Sublicensing Income” includes each and every payment received from a sublicensee 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 and 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

An Observation

- ❑ We used to find the three most contentious financial issues in negotiations were:
 - ❑ Royalty rate
 - ❑ Royalty stacking / offsets
 - ❑ Sublicense income sharing
- ❑ We found that these issues were enormously simplified by structuring the deal with:
 - ❑ A lower royalty rate
 - ❑ No stacking
 - ❑ “We don’t agree to stacking for royalty rates below 5%. You can afford a 4% royalty”
 - ❑ Passed through to sublicensees

Additional Information

Read the Featured Article of the Month ►



“Defining Sublicense Income to Avoid Problems Down the Road”, Ashley J. Stevens, *Journal of the Licensing Executives Society International (les Nouvelles)*, LIII, 1-10, March 2018;

Thank you for listening

Questions?