

9 Questions for a Territorial Split Deal

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#1 Why do you want a territorial split deal?



- Maximize total value
- Minimize spend
- Marketing muscle
- \$ sooner
- Data sooner (faster recruitment)
- Unique data (a special population, difference in standard of care comparator)

#2 Why not do a territorial split?



- More complex to manage multiple partners
- Taking away future sales can reduce the probability of a ROW deal.
 - Historically, China and Japan have been separable.
- Don't want to risk the bigger ROW deal with terms that will apply to your ROW partner?
 - Typically, the rights and obligations you accept are passed onto your sublicensee.
 - Bigger companies will not do a deal that is outside their way of operating.
 - STRUCTURE THE FIRST DEAL TO PERMIT THE 2nd DEAL = may prevent reciprocal terms
- Risk to optimal development, concern on safety results?

#3 What is your BATNA?



- You should always be building your Best Alternative to This Negotiated Agreement.
- Your alternatives might include
 - Raising more money
 - Developing the asset alone
 - Partnering with someone else
 - Stopping the program
- Knowing your alternatives enables you to make rationale decisions on negotiating with inevitable compromises

#4 Who does what?



- Shared coordinated global development program or separate development or importer?
 - Shared coordinated global development is much cheaper for the smaller territory but is more complicated to coordinate.
 - Separate development may be faster.
- Often, there is an attached development plan with significant changes to be approved (by rules or consensus)
- Is manufacturing coordinated or separate?
 - A supply and quality agreement should be entered for either path

#5 Who decides what in the licensed Territory?



- Joint (consensus), by rule for a topic, or by who is paying?
- Generally, not reciprocal (the originator sits on the licensee's committees)
- Often, the party holding the largest territory wants to have at least a veto over any decision that could hurt that territory.
- And the bigger company may not want to be obligated to a joint decision-making role.
- But each party will want to optimize for their own regulatory and commercial differences.
- The originator may want to retain rights to manufacture or do studies in the licensed Territory

#6 Who owns/prosecutes new data and new IP?



- The aim of a deal can be to get new data.
- Ownership of new data and new IP are a potential complication for any sublicensing deal. The bigger company/territory frequently controls IP and publication of data.
- Is there a right to reference regulatory filings?
- New IP can be from manufacturing trade secrets (not readily shared) or from licensed IP (requiring deal terms for the other party's territory).

#7 How are disputes handled?



- Each party would like its own law governing any dispute but often a neutral venue is chosen.
- Joint committees, then escalation (but a big company will want a delegate not the CEO).
- Finally, your sublicensee may prefer arbitration (with its concern of “splitting the baby”) versus court cases with huge uncertainties and time.

#8 Who takes risks of tax withholding, exchange rates and currency controls?



- In some territories, inflation can dramatically reduce the value of the local currency.
- Tax withholding from deal payments can be significant and differ by country.
- China currency controls may mean the money can't be transferred out of China. Payment into a local account may be less useful than money with no restrictions.

#9 What happens on termination at will?



- Can they terminate country by country?
- Is there an orderly transition to enable you to pick up from where they stop?
- Is there compensation (a reverse royalty) for their advancement of the program?

For all territorial deals

- Start with the aims for the deals, not the money
- Take your time
- Look at what they have done before
- Look at what others have done (pull SEC filed contracts)
- Summarize all along the way
- Work with an experienced transactions attorney
- Don't jeopardize the next deal-- think of the concerns of investors or the next partner
 - Information sharing
 - Decision making
 - Manufacturing tech transfer
 - Improvements
 - Dollars on value inflections
 - Etc, etc

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