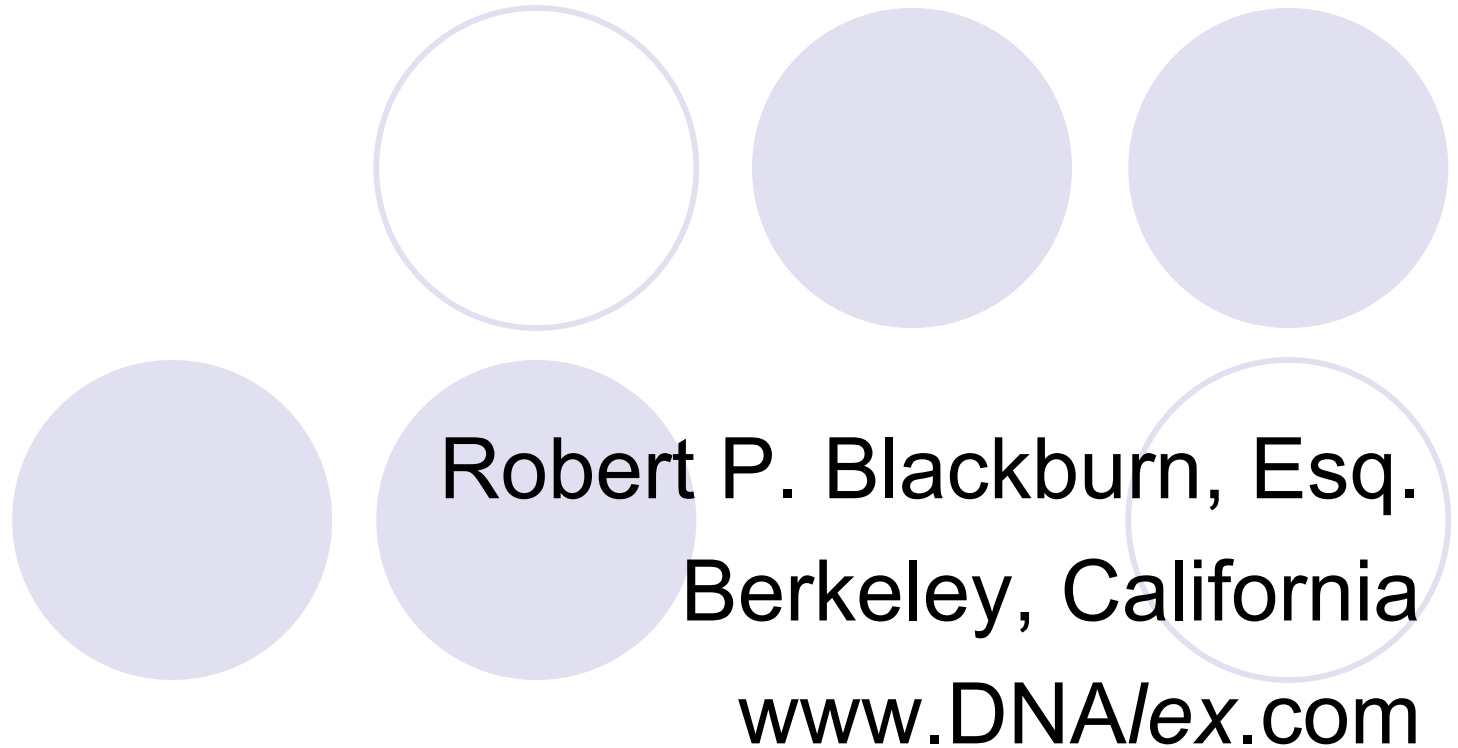


IP Strategy in BioPharma



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A decorative graphic at the top of the slide consists of two groups of circles. The first group on the left has a solid light purple circle on the left and an outlined light purple circle on the right. The second group on the right has a solid light purple circle on the left, an outlined light purple circle in the middle, and a solid light purple circle on the right. The word "Disclaimer" is written in black text, with the first group of circles partially overlapping it.

Disclaimer

Views expressed here are for the purpose of stimulating academic discussion only, and not attributable to any past, present or future client.



Introduction

- What will be covered
 - What is IP Strategy?
 - Elements of a Strategy
 - Strategy Team & Implementation

Why are we talking about Strategy?

- "A few years ago, the venture capital community was only beginning to really recognize the importance of intellectual property strategy for start-ups. Today, there is broad recognition among VCs of the value of a strong IP strategy."
 - Tom Bevilacqua, managing general partner of E*TRADE Venture Capital

Why are we talking about Strategy?

- Start-up funding
- Alliance/Licensing/Acquisition
- Market Position of Products
 - Freedom of Operation
 - Constraint on Competition

So What is a Strategy?



- It's not your same old prep & pros routine
 - Not driven by invention disclosures
 - A Strategy drives R&D
 - It's not reactive to regulatory outcomes
 - A Strategy anticipates and incorporates regulatory outcomes
 - It's not "home-country-centric"
 - Most of the world's pharma market is ex-US



So What is a Strategy?

- An “IP Strategy” is a business plan
 - It starts with an understanding the client's primary business plan
 - It defines how IP generation, IP acquisition, IP licensing, IP enforcement & IP defense supports the R&D, regulatory and commercialization aspects of the business plan



So What is a Strategy?

- Is that really something new?
 - The details look old?
- It is a new “lens” at which to look at IP
 - Proactive
 - Not just what comes out of the lab & the patent office



Elements of a Strategy

- Thorough Understanding of the Business Plan
 - Scalable
 - Company
 - Product Area
 - Product
 - Not Necessarily Static
 - Test base assumptions for IP “reality”
 - Iterative – becomes part of the Business Plan



Strategic Elements - Offense

- “Hey! I got a patent on your invention!”
- Big Deal
 - That’s the least important aspect of a patent



Strategic Elements - Offense

- Your client won't sue itself
 - Patents don't (directly) create freedom of operation
- Patents are “negative easements”
 - Thus, a valuable patent is one that stops a third party from doing something of significance to them that they want to do
 - Often, but not always, a patent on your client's product



Strategic Elements - Offense

- First task for the “offense”
 - Learn the field relevant to the business plan
 - Competition
 - Include hypothetical competitors
 - Public domain
 - “Scientific Commons” as a constraint on competition
 - Knowing the “prior art” and competitors’ direction gives you the high value targets



Strategic Elements - Offense

- Second task for the Offense

- Generate IP around the high value targets

- Home grown – ask yourself this question:

- “Can the head of R&D make an informed decision on the probable ROI to the company from IP generated program A vs. program B?”

- Acquired IP – ask yourself this question:

- “Does the head of BD have a shopping list for the target areas?”



Strategic Elements - Offense

- Third task for the Offense

- Do it all again for the “Downstream”

- Pre-clinical

- Can they generate data to support prosecution tactics (e.g., genus claims, 103 rebuttals)?

- Manufacturing

- Have they found something tricky about the molecule?

- Clinical

- Dosage, formulation, route of administration
 - Companion diagnostics

- Marketing

- Customer, patient management



Strategic Elements - Offense

- Fourth task for the Offense
 - Rest of the World
 - ROI of foreign filings
 - Market size and markets “affected”
 - Enforcement
 - Differences in subject matter
 - Method of treatment vs. 2nd Medical Use
 - “A bridge too far”
 - Exposure



Strategic Elements - Offense

- Fifth task of Offense
 - Mesh the patent strategy with the regulatory process
 - Project development timeline with:
 - Patent term
 - Patent term extension
 - NCE exclusivity
 - Data exclusivity
 - Orphan drug



Strategic Elements - Defense

- First task for the Defense

- Monitor the competition

- Patents & applications (Duh!)

- Business plan

- Feeds other tasks



Strategic Elements - Defense

- Second task for the Defense
 - Analyze upside of Peace vs. War
 - ROI of reduced investment in IP war
 - Can different market segments be addressed?
 - Are the IP portfolios complimentary?
 - Can product risk be shared?
 - Are expertises complimentary?
 - Consequences of losing to both sides
 - Is there a lose-lose risk?

Strategic Elements - Defense

- Third task for the Defense
 - Analyze the framework of a War
 - What is the commercial objective?
 - Expected cost and resource disparity
 - 1st to market or 2nd?
 - May need to map out both scenerios
 - How many countries?
 - Will victory in one country make product viable?
 - Is there an Achilles' heel country?

Strategic Elements - Defense

- Fourth task for the Defense
 - Prepare a War Plan
 - Move first or wait?
 - Challenge their patent, enforce your patent or both?
 - How much do you put at risk?
 - Counterattack
 - What country & forum?
 - Patent office or local courts
 - Jurisdiction
 - Speed & impact on other jurisdictions
 - Cost
 - Bar

IP Strategy Team & Process

- One person cannot do it all
 - Multiple expertises required
 - Involve foreign counsel early
 - Split bar
- One person can coordinate
- Regularly Review & Revise
 - Nothing is static – not your client's business plan, their competitors, and least of all the technology & the law



Thank You For Your Kind Attention

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