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Unlocking the Power of Branding: Elevate Your Life Sciences IP Strategy

Presented by: Alyssa Worsham, Wilson Sonsini; Brandon Leahy, Wilson Sonsini; and Dell Chism, Centessa Pharmaceuticals

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Agenda

- Introductions
- Developing a Branding Strategy – What, When, and Where to Protect
- Performing Trademark Clearance – Avoiding Third-Party Issues and Identifying a Protectable Brand
- Securing and Scaling Global Brand Protection
- Truth in Advertising: Navigating FTC Rules in the Digital Age
- Q&A

Today's Presenters

Alyssa Worsham
Partner | Wilson Sonsini
aworsham@wsgr.com

Brandon Leahy
Senior Counsel | Wilson Sonsini
bleahy@wsgr.com

Dell Chism
Vice President, Intellectual Property
Centessa Pharmaceuticals

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Developing a Branding Strategy – What, When, and Where to Protect

Developing a Branding Strategy

- What will be your potential trademarks?
  - House mark (trade name)
  - Proprietary platform name
  - Branded clinical trials
  - Drug names
  - Logos
  - Taglines
- What are your key brands?
  - Focus on your house mark and lead product name candidates
  - Slogans can be unprotectable in certain geos (EU) or fleeting in marketing departments
  - Study names are generally difficult to protect and register, but still check for risks

Developing a Branding Strategy

- When should you begin evaluating potential brands?
  - Start early with company name and evaluate product names months ahead of launch or regulatory review process
  - FDA proprietary name review process is independent of the USPTO trademark review process
  - The timing of clinical trials and commercialization will be meaningful
  - Keep in mind the “first-to-file” system prevailing in many markets
- What are your key geographies now and in the next few years?
  - Evaluate budget and identify most critical markets
  - If the company has already received a lot of PR (or it’s expected to) consider defensive filings even if no market plans
  - Consider how to avoid public attention on stealth product development
- Working with a branding agency
  - For potential pharmaceutical brand names, start with names likely to pass FDA scrutiny
  - Branding agency review of trademark clearance is a good starting place but insufficient to properly evaluate risks

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Performing Trademark Clearance

Clearance Considerations before Engaging Counsel

- Arguably one of the most important steps in brand protection process
- Assess nature and scope of the intended uses
- Evaluate protectability and risk of the brand
  - Is the mark too “descriptive”
  - Is the mark a common or trendy word?
  - Do you see other marketplace use for similar (if not the same) offerings?
  - If a pharmaceutical product name, have you obtained an opinion on the likelihood of FDA approval?
- Perform high-level cursory searches to save money on legal fees:
  - Google
  - Social media handles
  - USPTO database
- Domain availability or availability on corporate register are not dispositive

Formal Trademark Clearance – Avoiding Third-Party Issues and Identifying a Protectable Brand

- It is critical to properly assess availability and protectability across markets
  - Conduct initial high-level diligence directly or via branding agency
  - Identify the nature of the intended uses and the target markets
  - Engage counsel for a formal clearance process
  - Counsel should review a range of sources – trademark databases, business names, domain names, web hits, pharmaceutical databases
  - For product names, best to start with a broad list and narrow to 2-3 alternatives for further searching
  - Consider engaging foreign counsel in mission-critical jurisdictions
  - Beware of heightened scrutiny facing life sciences companies
- Better late than never
  - Even if a name is already in use, a search can provide valuable information to mitigate risk
  - Filing is not always the best policy

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Scaling a Global Brand on a Budget

Scaling a Global Brand on Any Budget: Broad Considerations

- Is the brand in use yet?
  - If not, consider ITU application in US and national applications in critical markets
  - If yes, where? Consider common law protection to date
  - If US mark is registered, consider leveraging the Madrid Protocol
- Do you have regulatory approval?
  - If not, relying on regulatory approval, consider filing for 2-3 alternatives.
  - If the company has already received a lot of PR (or it's expected to) consider defensive filings even if no market plans
- Tips
  - Focus on core word mark
  - Stylized filings can help if word mark presents challenges
  - Slogans can be unprotectable in certain geos (EU) or fleeting in marketing departments
  - Leverage long prosecution process to meet commercialization timeline

Scaling a Global Brand on a Budget: Make The Money Count

- Costly to implement strategy for every single product name, feature name, brand variation, tagline, logo, etc.
- What is the business' "house mark"?
  - Company name
  - House logo
- How will the business primarily use its mark?
  - Proprietary platform?
  - Pharmaceuticals?
  - Life sciences or medical device?
- How important is the brand to the company and its offering?
- Consider whether the logo or stylization will evolve overtime—with new funding comes more marketing budget.
- When to consider not filing
  - Descriptive marks can help educate
  - Mitigate risk

Scaling a Global Brand on a Budget: Key Geographies

- Trademark rights are territorial
- If budget is tight, lock in US registration and go from there when you can
- Expensive to implement full-blown strategy in every country around the world, even for larger companies
- Focus on your most important business territories over the next 3-5 years + defensive considerations
- Usual suspects:
  - US, EU, UK, Canada
  - New Zealand, Australia, Japan, Korea and HK
  - China, Turkey, Russia, India, Brazil

Scaling a Global Brand on a Budget: Trademark Filings

- File strategically in geographies that matter
- Cost-effective considerations:
  - Paris Convention filing window
    - Pro: Allows companies to stagger / push costs over six months; broad protection
    - Con: Can be expensive with national applications
  - Madrid Protocol / WIPO
    - Pro: Allows companies to file a single International Registration (IR) at the World IP Office (WIPO) and extend to multiple territories
    - Con: Limited protection; all filings/extensions are tied together
    - Hybrid option often advisable, using the Madrid Protocol to pursue "global" brand protection at manageable cost
  - EUTM Filing
    - Single application covers 27 member countries
- Beware of non-use vulnerability

Scaling a Global Brand on a Budget: Enforcement

- Enforcement is key to maintaining brand value
- Responsible for taking *reasonable* effort to police third-party brands
  - Not necessary or efficient to take action against every single minor issue out there
- Geographies of interest and flagrant infringement are most important
- Watch notices
  - Allow companies to be notified early re: third-party issues, which can save money in the long run

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Truth in Advertising: Navigating FTC Rules in the Digital Age

Who are the Advertising "Police"?

- **Federal Drug Administration (FDA)**
  - primary jurisdiction to regulate labeling and advertising of restricted medical products
  - FDA has primary responsibility for enforcement re labeling of FDA-regulated devices and prescription drugs
- **Federal Trade Commission (FTC)**
  - primary jurisdiction to regulate the truth or falsity of advertising for non-restricted medical products
  - FTC has primary responsibility for enforcement re advertising of most FDA-regulated devices
- **National Advertising Division of BBB (NAD)**
- **State AGs and Private Rights of Action**

FTC Regulation Update: Reviews and Testimonials

- FTC issued final rule in August 2024:
  - Prohibits fake or misleading consumer reviews or testimonials
  - Commission authorized to seek civil penalties against violators
    - Monetary fines of up to nearly ***$52K per violation!***
  - Liability expanded to include companies that knew ***or should have known*** about prohibited conduct
- Raises stake for companies that solicit consumer reviews

FTC Regulation Update: Reviews and Testimonials (cont'd)

- **Prohibited conduct includes**:
  - Creating, selling, or buying fake/false reviews or testimonials, including AI-generated fake reviews
  - Compensating/incentivizing consumers to write reviews that express particular sentiment (either positive or negative)
  - Using insider reviews and testimonials without clear and conspicuous disclosure of relationship
  - Misrepresenting that a company-controlled website/entity provides independent reviews or opinions, other than consumer reviews, about products/services that include the business' own products/services
  - Suppressing negative reviews
  - Buying/selling fake indicators of social media influence, e.g., followers or views generated by bots or hijacked accounts

FTC Regulation Update: Reviews and Testimonials (cont'd)

- **Key Takeaways**
  - Solicit reviews from actual consumers
  - Make neutral requests for reviews
  - Approach and rank all reviews neutrally
  - Provide clear and conspicuous disclosures
  - Conduct active monitoring

Social Media Marketing: Influencers and Endorsements

- **Endorsement**
  - Advertising message that consumers are likely to believe reflects an opinion of a party other than sponsoring advertiser
  - May be the same as advertiser's opinion
  - Must reflect endorser's honest opinion and cannot express something that would be deceptive if made directly by advertiser
  - Ad law substantiation requirements apply to objective statements made by endorsers
  - Endorsers must be bona fide users if their statements suggest so, and endorsers must have the expertise that they are represented as possessing
- **Influencers**
  - Macro, micro, and nano influencers can all be very persuasive in marketing
  - Create sense of community that celebrities and companies cannot replicate

Social Media Marketing: Influencers and Endorsements (cont'd)

- **Endorsement and Influencer Issues**
  - Emotionally compelling but not always deeply knowledgeable about the product (or research/back-up for claims about product)
  - Obligation to include risk factors?
  - Are "likes" or "retweets" equivalent to endorsement, or just merely opinions?
  - Is consumer "endorsing" product when they comment in social media post in exchange for free trial?
  - Can employee post about their company on their personal accounts?
  - Can companies pay their customers as courtesy for using their social media posts in marketing?
  - Must company track all social media endorsements?
  - How can a company monitor and track compliance for micro and nano influencers?

Social Media Marketing: Influencers and Endorsements (cont'd)

- ***Is social media message "sponsored"?***
  - Is speaker acting independently or acting on behalf of advertiser or its agent?
  - Facts and circumstances dependent:
    - Is speaker compensated by advertiser/agent?
    - Was product/service provided to the speaker for free by advertiser?
    - What are the terms of the agreement (if any)?
    - What's the length of relationship?
    - Has speaker previously received products/services? Is future receipt likely?
    - What is the value of the items or services received?
- **IF THERE IS A SPONSORSHIP RELATIONSHIP, THEN IT MUST BE DISCLOSED!**

Social Media Marketing: Influencers and Endorsements (cont'd)

- **Disclose Material Connection**
  - Disclosure of material connection required when sponsorship relationship exists
  - Material connection can be cash or in-kind services or other consideration
  - Endorser is the primary party responsible for disclosing the material connection
  - Advertiser not off the hook for failure of endorser to disclose—in fact, companies could be sued if sponsoring a post that omits material facts
  - Employees will always have material connection
  - As always, disclosure needs to be clear and conspicuous
  - Risks of non-compliance include FTC investigations, lawsuits and poor PR

Social Media Marketing: Influencers and Endorsements (cont'd)

BEST PRACTICES FOR ENDORSERS AND INFLUENCERS

- In-line, prominent disclosures in text are best
- Character and space limitations are no excuse
- Single disclosure may not be enough
- Be mindful of formats
- Will a viewer of video always see disclosure?
- Will disclosure travel when picked up on mobile device?
- No magic words. But consider indicators such as:
  - #sponsored, #paid, #ad
  - #spon, #partner, #ambassador are considered too vague
- Use above the break in text

Social Media Marketing: Influencers and Endorsements (cont'd)

- **BEST PRACTICES FOR ADVERTISERS AND BRAND OWNERS**
  - **Clear External Guidelines**. Establish written guidelines and train endorsers and influencers.
  - **Contractually Bind Social Media Endorsers**. Require endorsers and influencers to disclose material connections and include any required information about medical devices.
  - **Monitor**. Be diligent in monitoring endorsers and influencers and in taking prompt action.
  - **Careful @ What You Are Incentivizing**. Context may determine whether a "like" is incentivized action requiring disclosure.
  - **Use Technology**. Use technical monitoring tools (e.g., marketing intelligence or monitoring services such as TweetDeck or Hootsuite).
  - **Retain Records**. Keep written record of your monitoring and enforcement.
  - **Clear Internal Policies and Control**. Limit who speaks for company. Assign central responsibility for managing endorsements and influencers.
  - **Standardize Disclosure Practices**. Require that all disclosures be consistent and complete.
  - **Audit Use and Benefit**. Evaluate benefit of use of free products and payment practices.

Claim Substantiation: FTC General Principles

- **FTC focus:** whether claims for a product are truthful, non-misleading and substantiated by "competent and reliable" scientific evidence
  - Substantiate before disseminating
  - Advertiser responsible for all reasonable interpretations
  - Timely and current
  - Advertisers must possess at least the level of substantiation claimed in ad
    - "Doctors recommend. . ."
  - Consumer surveys, expert testimony
  - NOT newspaper articles, sales materials, anecdotes
  - Responsibility for adopting third-party claims

Claim Substantiation - What is "Mere Puffery"?

- "Mere Puffery" does not require substantiation
- Statements of opinion that reasonable consumers would not interpret as factual claims to be relied upon
- Usually general, vague, subjective, incapable of measurement, and often hyperbolic
- Court decisions in this area are notoriously subjective

Substantiation Must Closely Tie to Specific Claim

- Competent and reliable scientific evidence is required to substantiate all claims, and the evidence must be relevant. If relying on a study, the endpoints must match the claim.
- **Claim**: Effective at eliminating 99.99999% of COVID-19
  - Support: University of Minnesota study
  - SARS-COV-2 was not used in the actual study
- **Result**: NuWave compelled to modify claims: "OxyPure is Calculated to Remove 99.9999% of Coronavirus Surrogate from the Air in Areas up to 1200 Square feet in 6 Hours!"

Establishment Claims

- Establishment claims assert that there is scientific evidence that "establishes" the truth of the advertiser's claim.
  - "Tests prove . . ."
  - "Studies show . . ."
  - Less explicitly, images showing a treatment or test being provided by a health professional.
- Held to high standard of scientific proof.
- Performance benefit must be statistically and clinically significant.
- Like all health-related claims, must be supported by competent and reliable scientific evidence.
- Tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, which have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- Establishment claims are open to attack on the ground that the underlying test does not support or verify the claim.

Establishment Claims – ZyCal Cyplexinol – FTC Case

ZyCal advertised pills containing Cyplexinol, a dietary supplement, under the brand Ostinol. The product was promoted as a bone and cartilage growth stimulant that could relieve joint pain.

Claims

- clinically proven to "stimulate cells to grow bone tissue"
- "proven for 40 years and used clinically for 20 years to grow bone"

FTC Decision

- Claims were deceptive, false, and unsubstantiated. ZyCal was barred from making any similar claims about bone and cartilage growth unless backed by "competent and reliable scientific evidence, including randomized clinical trials."
- "This settlement is an important reminder that health-related advertising claims require rigorous substantiation in the form of competent and reliable scientific evidence."

Comparative Advertising

- Comparative advertising that is truthful and not misleading is generally permissible.
- General claims of superiority over a comparative product that are vague or indeterminate are viewed as mere expressions of opinion. For example, “better than” claims are often merely puffery.
- Comparative/establishment claims can be vulnerable to attack – a plaintiff can simply assert that the underlying test does not support or verify the claim, placing the burden on the advertiser.
- Tests can be undermined as unreliable or not establishing the proposition for which they were cited (if, for example, they stand for some other proposition or are contradicted by other tests).
- Product comparisons should generally be apples-to-apples. If comparing Company A’s product to Company B’s product, ensure the products at issue (i) have the same function or intended purpose and (ii) are the most relevant/similar products for comparison of the respective companies.
- Product comparisons that are considered apples-to-oranges – where things that are non-comparable are portrayed as otherwise equivalent – are generally considered literally false. Such comparisons can be permissible, however, if all material differences are clearly disclosed and the advertisement does not imply that the competitor does not have a more similar product.
- If medical products have not been tested against one another in a well-controlled, head-to-head clinical study, specific claims about superiority may be considered false, misleading, or deceptive.

Comparative Advertising – Citracal Calcium Dispute (NAD Arbitration)

Claims

- "Citracal is twice as well-absorbed as calcium carbonate."
- "Calcium citrate is better absorbed than calcium carbonate by about twenty-five percent."
  - Challenger: Claims are false. Well-conducted clinical studies prove that calcium citrate and calcium carbonate are equally well-absorbed when taken with food. Claims are also misleading because they imply that calcium citrate (Citracal) works better than calcium carbonate products, such as challenger's product.
  - Advertiser: Submitted two studies concluding that 500 mg of calcium citrate from Citracal was significantly better absorbed than 500 mg of a calcium carbonate supplement when both were taken with a meal.

Decision

- Various studies comparing calcium citrate and calcium carbonate have reached different conclusions. One study is not definitive.
- The advertiser here claims specific and quantifiable product use results – claims which by their specificity require competent and very reliable (and directly applicable) scientific support.
- The evidence provided was insufficient to support the advertiser's unqualified, specifically quantified, claims of calcium absorption.

Comparative Advertising – Guardant Health v. Natera Litigation

- Guardant Health's Reveal product: a colorectal cancer diagnostic based on a blood draw.
- Natera's Signatera product: a colorectal cancer diagnostic using tumor sampling and sequencing.
- Natera claimed its Signatera product:
  - Had a lower "failure rate" than Reveal
  - Had superior "pre-surgical sensitivity"
  - Had superior "diagnostic lead time"
  - Had superior post-surgical predictive value

Natera investor presentation:

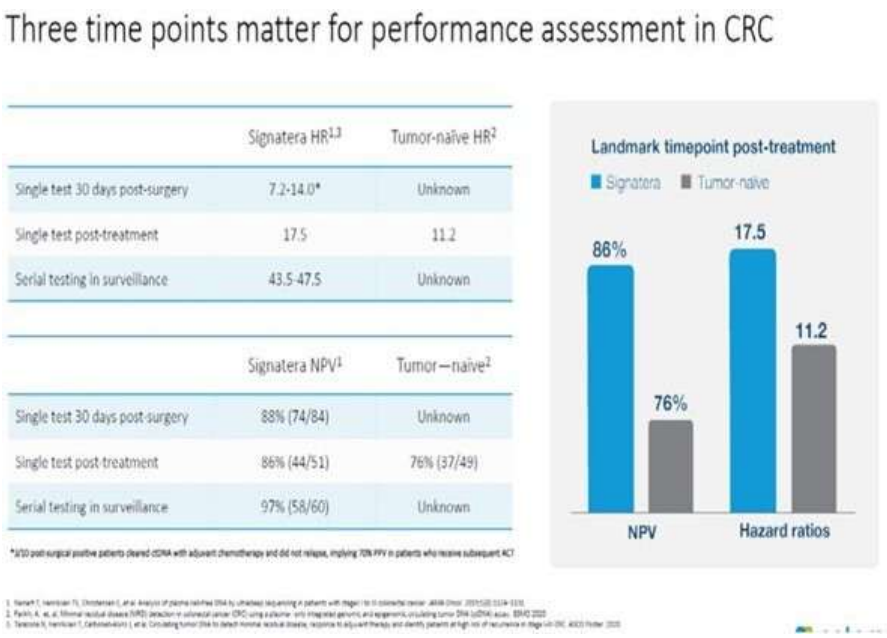
Signatera vs. Reveal performance comparison

	Signatera	Reveal
Validation data published or presented (# patients analyzed)	> 2,000[1,2]	< 150[4,5]
Pre-surgical sensitivity in CRC	89-94%[1,3]	47%*[4]
Failure rate in CRC – tissue and plasma combined	< 3%[3]	12-14%[4]
Number of blood tubes required	2	4
Diagnostic lead time vs. radiographic recurrence in CRC (avg)	8.7 months[1]	~4 months*[4]
Post-surgical NPV/PPV in CRC (30 days post-surgery)	88% / 100%**[1]	not reported[4]
Serial longitudinal NPV in CRC	97%[1]	82%[4]
Serial longitudinal Hazard Ratio in CRC	43.5[1]	11.4[4]
Serial longitudinal sensitivity in CRC	88-94%[1,2]	69%[4]
Quantitation of ctDNA burden for monitoring purposes	Tumor copies per mL	none

Comparative Advertising – Guardant Health v. Natera Litigation

- Natera: Signatera's "test performance" is "unsurpassed," while tumor naïve tests (like Reveal) have "unknown" performance metrics.
- Guardant: Natera's claims of superiority were false, misleading, and deceptive.
  - No head-to-head studies were performed.
  - Natera relied on different studies, run in different countries, using different test protocols and methods, and examining different patient populations.
  - Natera made misleading statements not supported by its own studies. For example, "pre-surgical sensitivity" metrics were irrelevant because neither product was used as a pre-surgical diagnostic.

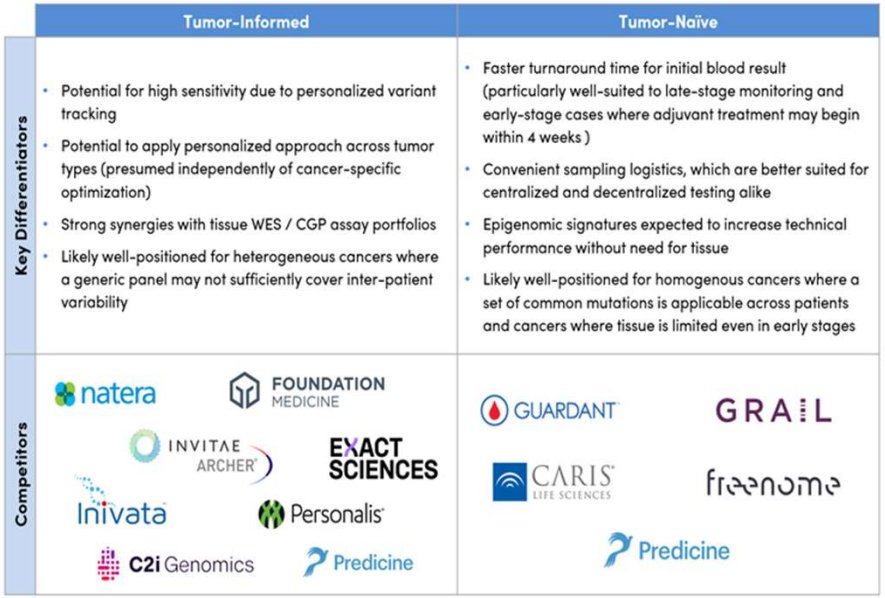
Natera chart:



Comparative Advertising – Guardant v. Natera Litigation

- Guardant: Natera's use of "apples-to-oranges" comparison renders the ads literally false; the analysis could not legitimately be used to claim that one product is superior to the other.
- Court instructions to jury:
  - Claims using an "apples-to-orange" comparison are literally false by necessary implication where things that are non-comparable are portrayed as otherwise equivalent.
  - Claims based on peer-reviewed studies can still be literally false if the claims are not supported by the study.
- Jury:
  - Natera engaged in willful false advertising.
  - Natera liable for $292.5 million in damages (actual and punitive).

Third-party Market Analysis



Claim Substantiation and Comparative Advertising – Some Practical Takeaways

- Back-up your claims with reliable, competent, and directly applicable scientific support
- Diligently maintain files with up-to-date backup
- Narrowly tailor claims to scientific evidence
- All medical product or diagnostics claims, particularly establishment claims, have a particularly high bar
- Qualifiers are unlikely to save the day
- Only make apples-to-apples comparisons
- Questionable advertising practices of competitors is not an excuse

Q&A

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Partner | Wilson Sonsini
aworsham@wsgr.com

Senior Counsel | Wilson Sonsini
bleahy@wsgr.com

Vice President, Intellectual Property
Centessa Pharmaceuticals