

Key Aspects of Intellectual Property Life Cycle Management and the Developments Affecting Them

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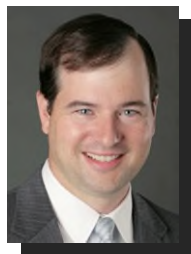
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INTELLECTUAL PROPERTY DEVELOPMENTS SHAPING PRODUCT LIFE CYCLES

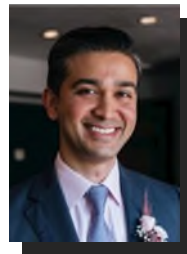
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BACKGROUND ANALYSIS



STEP ONE: UNDERSTANDING THE MARKET AND WHAT A COMPANY CAN ACCOMPLISH

- Understand the limitations – Cannot avoid or vet all IP issues
- Identify Risk Tolerance
 - Stage of company's growth and where product fits within that growth
 - Where is the product in development
 - Time to market; base theory for exclusivity, i.e., foundational patent and regulatory protection, and ability to extend
- Identify Competitors
 - Existence of competing product, stage of competitor's development, how competitor acts in the marketplace



LIFE CYCLE MANAGEMENT – STARTS DURING RESEARCH

IP Pyramid Analysis

- Identification of Strategy for Protecting Your Solution & Potential Alternative Solutions
 - Focus on platform technology – obstacle to competitor’s solution and potential revenue stream
 - Protection of Company’s Solution
 - Product patents
 - Method of Use patents
 - Manufacturing patents
 - Increased importance for biologic products

IMPORTANCE AND TIMING OF THIRD-PARTY MONITORING

Benefits	Drawbacks
Allows for understanding of market landscape	Difficult to craft proper searches because of fluidity of research program
Early identification of barriers (that may allow revisions to program) to avoid	Perceived barriers may cause company to forgo potential valuable opportunities
Identifies market participants and potential partners	Commitment of personnel and financial resources that can be put to better use
Provides potential to stake out unique IP portfolio	Information may be exploited by another party in a patent dispute to assert knowledge and lack of basis to pursue infringing activities



RESULTS OF ASSESSMENT

Format of Final Assessment

- In-house assessment
 - Provides guidepost for advising business decision-makers and develops evidence of reasonableness
- Outside counsel presentations
 - Memorializes FTO and LOE assessments to provide support for historical decisions and identifies issues that may require detailed assessment closer to market entry
- Outside counsel formal opinions
 - Reserved for highest risk in which litigation is fairly certain

RECENT DEVELOPMENTS

IMPACT ASSESSMENTS OF LOE

PATENT ELIGIBILITY – 35 U.S.C. § 101

*Two-Step Framework provided by Alice Corp. and Mayo Collaborative Servs.**

- Is the claim directed toward patent ineligible matter, including an abstract idea, law of nature, natural phenomena, or product of nature?
- If yes, then considering the claim elements and their combination, does the nature of the claim transform it into patent eligible material?

Supreme Court Inactivity and Congressional Activity

- Supreme Court has denied cert. over the last several years even in view of the Solicitor General's advice to take up certain cases
- Patent Eligibility Restoration Act of 2023
 - Replace judicially created test with five eligibility exclusions
 - Human gene or natural material not considered unmodified if isolated, purified, enriched, or otherwise altered by human activity

* *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

** See Supreme Court denial of cert. on May 15, 2023, in *Interactive Wearables, LLC v. Polar Electro Oy* and *Tropp v. Travel Sentry, Inc.*

JUDICIALLY CREATED OBVIOUS-TYPE DOUBLE PATENTING

Impact of life cycle planning

- Constitutionality?
 - *In re SawStop Holding LLC*, 2022 WL 1073339 (Fed. Cir. 2022) (Fed. Cir. R. 36 affirmance), *cert. denied* 143 S.Ct. 202 (2022)
- Increased reliance by Examiners on rejecting unrelated cases
 - Expands available prior art for examiners because can include unpublished patent applications
 - May be difficult to argue around with certain examiners
 - May result in building a record before the patent office that may be used against patent later
- Key decision to accept a terminal disclaimer



ENABLEMENT AND WRITTEN DESCRIPTION

Amgen v Sanofi, 598 U.S. 594 (2023)

- Confirmed the need to enable the “full scope”
 - Noted specification may enable if it “discloses ‘some general quality . . . running through’ the class that gives it ‘a peculiar fitness for the particular purpose’”
- Use of Means-Plus-Function Claiming for Proteins
 - *In re Xencor*, 16/803,690 – PTAB decision dated 1/10/2023
 - Held that “means for binding human C5 protein” failed to meet written description requirement



PROTECTING LOE BY LIMITING PUBLIC DISCLOSURE

Minerva Surgical, Inc. v. Hologic, Inc., 59 F.4th 1371 (Fed. Cir. 2023)

- Federal Circuit upheld summary judgment of public-use bar to patentability
 - Showcasing devices at trade show and with interested parties, such as potential investors and physicians, met requirements for public disclosure under pre-AIA statute
- How do you balance the need to allow investors and partners to understand status of research while maximizing potential to protect?
 - Advising business development personnel
 - Ability to effectively use non-disclosure and confidentiality agreements



U.S. PATENT GRANT PROCEEDINGS – POTENTIAL TOOL VERSUS POTENTIAL RISK

Post-Grant Review and Inter-Partes Review – Do they strike the correct balance?

- Within nine months of patent issuance PGRs provide option to challenge patents filed after ____ based upon all grounds
- IPR can challenge any patent based upon printed publication
- Potential issue with challenging during product development is standing to appeal
- PREVAIL Act
 - Jurisdictional requirement – sued or threatened with infringement
 - Limits on multiple proceedings before the PTAB and parallel proceedings in district court and ITC
 - Prevents institution of IPR if final adjudication exists from federal court or ITC
 - Alter evidentiary standard to “clear and convincing”



SKINNY-LABELING IMPACT OF LOSS OF EXCLUSIVITY ASSESSMENTS

GSK v Teva, 7 F.4th 1320 (Fed. Cir. 2021), *en banc denied* 25 F.4th 949 (Fed. Cir. 2022), *cert. denied* 143 S.Ct. 2483 (2023)

- Federal Circuit reversed district court grant of JMOL of non-infringement and reinstated jury verdict of induced infringement of a claim to method of decreasing mortality caused by congestive heart failure
 - Despite carve-out, Court concluded that sufficient evidence existed in remaining portion of label to support jury verdict
- Does potential for skinny label affect decisions in product development?
 - Small molecules – potential for off-label use of generic for removed indication
 - Biologics – reduce chance interchangeability designation

AI'S IMPACT ON DUE DILIGENCE

IP Protection Regimes

- Patents
 - Uncertainty related to inventorship and application of certain patentability standards, e.g., §§ 101, 103, and 112
- Copyrights
 - Training data and fair use questions
- Trade secret
 - Allows protection of all aspects of AI, but only against those that wrongly acquire
- Contract
 - Until increased clarity of scope of IP protection will be key to define rights and obligations AI and results

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