Patent Life Cycle Management: Adding Value and Controlling Costs

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More than tracking PCT filing dates and paying annuities
Goal: Add to the valuation of the commercialization effort throughout the life cycle of the patent portfolio.
Patent Life Cycle Management is not just a patent function but rather it is a significant part of the larger commercialization effort.

- Patent lifecycle can span 25 years or more.
- Technology, competition, markets and industries change significantly during this period.
- Approach should be part of the larger commercialization plan and tailored to the technology, market and industry.
- Approaches vary on maturity of the technology, company and market.
  - Video Rental Industry – Remember going to the video store to rent a DVD.
  - Internet Service Provider Industry – Remember the dial-up companies.
  - Publishing Industry – Remember paperback books.
Topics we will cover in today’s presentation

• Life Cycle Management Team – Major Stake Holders.

• Basics of Patent Life Cycle

• Overlaying the Patent Life Cycle with the rest of the development and/or commercialization plan.

• Specific Concerns
  • Early Stage Endeavors
  • Software and Tech
  • Life Sciences and Pharmaceuticals.
The Team & Major Stakeholders

- Requires a multi-disciplined approach
- Team make-up and stakeholders can change as technology and patent portfolio mature.
- Possible key players can come from:
  - R&D
  - Product Development
  - Manufacturing
  - Marketing
  - Competitive/Business Intelligence
  - Finance
  - Legal.
Complications in forming & maintaining team

- 25 year endeavor
- No one person or department has all the information
- Technology and product development move faster than the USPTO
- Regulatory complication
- Lack of market information or competitive intelligence.
Recommendations for a successful patent life cycle management team.

- Identify a responsible person early - should have visibility across multiple functions.

- Limit team make-up to those functions and people that are appropriate for the maturity of the technology, company and IP.

- Identify milestones in the commercialization effort and revisit your team make-up at those milestones.
  - Development Milestones
  - Validation
  - Regulatory
  - Finance

- Milestones also give the team something to manage to.
Basics of Patent Life Cycle

• The patent process, both US and International, has certain hard deadlines and milestones that must be planned for.

• And with these hard deadlines there are associated costs, which can be significant. Waiting until the last minute typically adds to the costs of the portfolio.
Patent Time Line:

- **Pre – Filing:** Be aware of possible bar dates.
  - Public disclosure or use of the invention typically starts a one year grace period in the US from which the filing must occur.
  - No grace period in foreign jurisdictions.
  - Bottom line – file before public disclosures or public uses of the invention.

- **Consider Provisional Filing:** Consult with IP Counsel.
  - Provisional patent applications can be a good method of securing a filing date before a public disclosure.
  - With first to file patent reform, provisional patent applications may be a good strategy.
Patent Life Cycle Management

Patent Time Line:

- **Initial Patent Filing:**
  - At anytime if no public disclosure
  - Provisional or utility application filed within one year of public disclosure.
  - Utility application filed within one year of provisional filing.
  - PCT filing within one year of initial filing.

- **Publication:**
  - Within Eighteen months after filing the non-provisional utility application or the PCT application, the application is published.
Patent Time Line:

- **Office Actions:**
  - Typically between eighteen and thirty months after the initial filing, we should receive a first office action on the merits.
  - Several iterations of office actions and responses to the PTO may be necessary before the application is allowed and issues.

- **PCT Nationalization:**
  - Within 30 months after filing a non-provisional utility application or filing a PCT application, individual countries must be designated for international patent protection.
Patent Life Cycle Management

Patent Time Line:

- **Annuities for pending applications:**
  - Most foreign jurisdictions require an annuity or annual fee to maintain the pendency of the application in the jurisdiction.

- **US Issuance:**
  - Consider continuation practice
  - US Maintenance fees are due at 3.5, 7.5, and 11.5 years.

- **Foreign Issuance:**
  - Consider foreign continuation practice.
  - Maintenance Annuities are also required in most foreign jurisdictions.
Patent Life Cycle Management

Patent Time Line:

- Post Grant Review and Post Grant Challenges:
  - After the patent issues, it can be subject to post grant challenges within the USPTO and foreign patent offices.

- Patent Term – 20 years from the filing date.
Commercialization Timeline and Milestones:

- Commercialization is technology and industry-specific.
- Technology and particularly product life cycles vary significantly depending on the industry and the product.
  - Software
  - Tech
  - Consumer Products
  - Industry & Manufacturing
  - Life Sciences
Patent Life Cycle Management

Commercialization:

- Science & Technology
- Business & Marketing
- Finance

Success
Commercialization: Milestones and Timelines have been extensively studied.
# Commercialization: Common Milestones

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Integrating the Patent Life Cycle Management with the commercialization plan.

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<td>• Initial issuance</td>
<td>• Patent life extension strategies</td>
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<td>• Continuations and additional filings</td>
<td>• Assertion</td>
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Integrating the Patent Life Cycle Management with the commercialization plan.

**Invention**

- Basic Research
- Technical Feasibility

- Consider early filings to secure earliest possible filing date.
- Consider competitive and patent landscape
- Watch for public disclosures
- Be forward looking, consider all fields of use
- Budget and Finance in accordance with business or development plan.
Integrating the Patent Life Cycle Management with the commercialization plan.

- Work with stakeholders to identify patent portfolio strategy.
- Look for additional IP in the product prototypes, beta-tests, optimizations, debugging, clinical trials and responses to regulatory concerns.
- Be mindful of state of the art, competitive environment.
- Budget and Finance.
Integrating the Patent Life Cycle Management with the commercialization plan.

### Commercialization

- Sales
- Derivative Products

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<td>Exit Strategies</td>
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Specific Concerns: Life Sciences and Pharma

- Cost to drug and life sciences developers is increasing each year.
- Regulatory environment adds to that cost.
- Fewer new drugs and products in the pipeline.
- Pressure extend product lifespan to recoup costs and support pipeline.
- Pressure for generics to break into profitable technologies.
Specific Concerns: Life Sciences and Pharma

As a result, much attention is given to the later stages of the patent and product life cycle management.

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Specific Concerns: Life Sciences and Pharma

- Extend Initial Term as much as possible
  - Patent Term Extensions

- Use second generation patents
  - Regarding Compounds:
    - Second Therapeutic uses
    - Changes in formulations
    - Crystalline polymorphs
    - Single enantiomers
  - Regarding Devices and Diagnostics:
    - Changes in methods, software, control systems
    - Changes in components, interoperability, geometry.
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Patent Life Cycle Management

- **Patent Term Adjustment (PTA)**
  - Governed by 35 U.S.C. § 154(b)
  - Meant to compensate for USPTO delays examining and issuing patent
  - Ensures that “no applicant diligently seeking to obtain a patent will receive a term of less than 17 years”

- **Patent Term Extension (PTE)**
  - Governed by 35 U.S.C. § 156
  - Meant to compensate for delays in regulatory approval process for pharmaceutical and other products subject to pre-market approval

- Total Patent Term = “Standard Term” + PTA + PTE
Patent Term Adjustment (PTA)

- **PTA = (Days of PTO Delay) – (Days of Applicant Delay)**
  - Can have days added to patent term, but can never have days subtracted (PTA ≥ 0)
  - PTA = 0 if applicant delay equals or exceeds PTO delay
- **Eligibility:**
  - Available to applications filed on or after May 29, 2000
  - For U.S. national phase applications, PCT filing date must be on or after May 29, 2000
- **Rules and Regulations Governing PTA:**
  - 37 C.F.R. §§ 1.702 – 1.705
  - M.P.E.P. §§ 2730 - 2736
Patent Term Extension (PTE)

- Purpose is to remedy loss of patent term due to delays in regulatory processes for pharmaceuticals and other products subject to pre-market approval
- Governed by:
  - Statute: 35 USC §156
  - PTO Rules and Regulations
    - 37 CFR §§ 1.710 - 1.791
    - MPEP §§ 2750-2764
Eligibility for PTE

• Eligible patents must claim:
  • A product subject to regulatory review before commercial marketing or use
    • Human drugs, antibiotic drugs and human biologics
    • Food additives and color additives
    • Medical devices
    • Animal drug products
    • Veterinary biological products
  • Method of using product subject to regulatory review
  • Method of manufacturing product subject to regulatory review
Eligibility for PTE (cont’d)

• Product must have been subject to regulatory review before commercial marketing or use

• Product must be specifically recited in the claim
  • Cannot rely on “comprising” language to argue product is inherently included.
    • See, for example, Vusion (US 4,911,932), March 19, 2009.
  • Patent claiming metabolite of approved prodrug is not eligible
    • The claimed ingredient must be present in drug-product when administered
      • Hoeschst-Roussel Pharmaceuticals, Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997)
  • Unclear if patent only claiming product/use/manufacture by equivalents (but not literally) is eligible for PTE
Eligibility for PTE (cont’d)

- Only granted patents eligible for PTE
  - Can not file PTE application until patent issues
- Must file application for PTE before patent expires
  - Can file before regulatory approval if patent would expire before end of review period
- Must file application for PTE w/in 60 days after approval
- Only one PTE granted per product per patent
  - Patent must not have been previously granted PTE under § 156
  - If patent covers two distinct products, and both are subject to regulatory review, only one extension of the patent is possible
Specific Concerns: Life Sciences and Pharma

- Extend Initial Term as much as possible
  - Patent Term Extensions

- Use second generation patents
  - Regarding Compounds:
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  - Regarding Devices and Diagnostics:
    - Changes in methods, software, control systems
    - Changes in components, interoperability, geometry.
Second Generation Patents - Pharma

- Consider additional filings with each new development.

- Filings directed to additional therapeutic uses.
  - Claims to a further medical use of a substance for which a therapeutic use was known.
  - Consultation with IP Counsel is important as claim format and type of second use can impact validity depending on jurisdiction.
Second Generation Patents - Pharma

- **Changes in formulation**
  - Benefits can include improved delivery, extended shelf life, etc.
  - Can be useful marketing tool over generic.

- **Crystalline polymorphs**
  - Directed to different crystals of complex molecules.
  - Benefits can include stability, shelf life, better production, improved bioavailability, etc.
  - Can be useful marketing tool over generic.
  - Be mindful of validity concerns
Second Generation Patents - Devices

- Consider new filing with each new generation or improvement of the product or process.

- Improvements in software, components, interoperability, user interface, materials and geometry can provide areas for new filings.
Specific Concerns: Early Stage Endeavors

Attention is typically focused on the first stages of patent and product life cycle management.

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Specific Concerns: Early Stage Endeavors

- Consider financing milestones and early exit scenarios

- Emphasis should be on broad portfolio potential
  - Early filing dates relevant to market
  - Treatment of multiple embodiments and fields of use.
  - Basic diligence
  - Early allowances can be beneficial.

- Consider targeting a portion of portfolio to strategic partners to attract investment, induce buy out.
Specific Concerns: Other Industries such as, Tech, Software, Consumer Products, Manufact’g.

Attention is typically given to the middle and later stages of the patent and product life cycle management.

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Specific Concerns: Early Stage Endeavors

- Consider financing milestones and exit scenarios

- Emphasis should be on broadening the portfolio
  - Revisit portfolio and consider additional filings with each product or technology validation.
  - Consider standards and regulatory environment.
  - Consider Competitive Landscape,
    - targeted filings directed toward white space or competitive space.
  - Preview derivative products and product integration.
Conclusion and Take-Aways

- Integrate Patent Life-Cycle Management into the overall commercialize plan.
- Identify the right team.
- Revisit the life-cycle management plan often, involving necessary stakeholders.
- Build portfolio potential relevant to the market.
- Expand the portfolio as products and market develop.
- Extend initial patent terms.
- Use second generation patents.
Questions?

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