Freedom to Operate: Identifying a Clear Field and Keeping It; a Large Company’s Perspective

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Freedom to Operate for Internal Product Development and Potential Acquisitions
Edwards Lifesciences

- Previously the CardioVascular Group of Baxter Healthcare Corporation
- Spun off from Baxter on April 1, 2000
- Traded on the NYSE
- Approx. $1 Billion in Annual Sales; Annual R&D Spending approx. $100 M
- 5000 Employees
- World leader in tissue heart valves and hemodynamic monitoring catheters
Internal Product Development

• Decision to enter new field or develop a new product in our current field

• Evaluate IP landscape by conducting broad patent searches in the technology area
  – Identify broad or blocking IP, if any
  – Determine whether we will have freedom to operate for the proposed product concept
  – Identify patents that need to be purchased or licensed, if any
  – Identify patents that may add value to our portfolio but do not present immediate FTO issues
Internal Product Development

- R&D begins to develop and propose product or process designs with IP landscape in mind
- Inside patent counsel is kept apprised of proposed designs and additional patent searching is conducted as new designs are proposed and as patent applications are filed
- When product design is finalized and just before commercialization, additional patent searching is conducted to confirm FTO
- Throughout the process, ongoing keyword searching is conducted on a weekly or monthly basis to keep the IP landscape updated
Due Diligence for Potential Acquisition

• Review IP Portfolio of Target Company, issued and published applications, pending unpublished applications (under confidentiality agreement)
• Meet with lead R&D person to better understand the technology and learn about any known IP issues, e.g., freedom to operate issues, ownership issues, potential to obtain dominant IP position
• Meet with Patent Attorney to learn more about the IP portfolio and freedom to operate issues
• Conduct freedom to operate and patentability searches
Upsides

• Dominant IP Position or Strong Likelihood of Acquiring Dominate Position
  – Earliest filing dates, or early filing dates and potential for provoking interference with holder of dominant IP

• Freedom to Operate
  – Technology does not appear to infringe third party patents, or there are strong noninfringement positions on third party patents
Upsides

• Target company has good patent coverage on its own technology or approach, with pending applications

• Target company proactively looking to acquire or in the process of acquiring related IP in the field from Universities or individuals
Major Concerns or Red Flags

- We discover freedom to operate issue previously unknown to target company
- Target company does not have freedom to operate opinions or has weak opinions
- Target company not aware of IP landscape
- Target company does not have clear title or exclusive rights to IP, e.g., assignment from one coinventor, but not the other
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Helping patients is our life’s work, and life is now Edwards Lifesciences