

Strategic Patent Searching: Now a Viable Tool For Guiding Your Life Sciences Product to a Successful Commercial Launch

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Roadmap

- ▶ Recent developments in patent law that make patent searching more viable
- ▶ Strategic use of patent searching in life sciences/pharma industry
- ▶ Practical considerations for setting up patent searching program

Willful Infringement

- ▶ Longstanding distrust of patent searching because of threat of willful infringement
- ▶ Patent infringement suits almost always involve allegation of willful infringement
- ▶ If willful infringement found, court can *triple* damage award
- ▶ Can have huge impact on company's exposure

Willful Infringement – cont'd

- ▶ Absolute defense to willful infringement – no knowledge of patent
- ▶ Extensive patent searching leads to greater risk of willfulness finding in subsequent litigation
- ▶ Acts as a deterrent to patent searching

Willful Infringement – cont'd

- ▶ Knowledge of patent not enough to establish willfulness
- ▶ For last 20 years, courts have imposed duty of due care:

Where . . . a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, *inter alia*, the duty to seek and obtain competent legal advice from counsel *before* the initiation of any possible infringing activity.

- ▶ Makes patent searching time consuming and expensive

In re Seagate Technology

- ▶ Patent infringement suit brought by Convolve against Seagate over hard drive technology
- ▶ Willful infringement issue appealed to Federal Circuit
- ▶ In August 2007 Federal Circuit issued decision:
 - Duty of due care abolished
 - No affirmative duty to obtain advice of counsel
 - Implemented *recklessness* standard

Impact of *Seagate* on Patent Searching

- ▶ Patent searching not the minefield it was before
- ▶ No longer need to have as close a look or obtain legal opinion for every patent found
- ▶ Opens door to more forward-looking uses of patent searching

Impact of *Seagate* – cont'd

- ▶ *Seagate* does not entirely remove willful infringement risk
- ▶ Can still be liable if conduct is “reckless”
- ▶ But recklessness standard adopted by Federal Circuit not entirely clear

Patent Reform Legislation

- ▶ Proposed legislation: patent owner required to send written notice of infringement **as a prerequisite** to making willful infringement charge in a law suit
 - Notice must identify patent and explain details of infringement
- ▶ Would open the doors to truly risk-free patent searching
- ▶ Legislation presently stalled in Congress, but possibility over next several years

Strategic Use of Patent Searching

- ▶ Use patent searching strategically to guide pharmaceutical or biologic product through development cycle
 - Development cycle for pharmaceutical product is lengthy and incredibly resource intensive
 - Often takes years to reach point of commercialization

Strategic Use of Patent Searching – cont'd

- ▶ Conduct patent searches on a regular basis throughout development cycle
 - During development or identification of target compounds
 - At start of *in vivo* studies
 - After developing manufacturing process
 - Immediately before filing of IND
 - After each clinical trial phase
 - Immediately before filing of NDA

Strategic Use of Search Results

- ▶ Comprehensive searching provides constant flow of patent information
- ▶ Benefit: early warning of potentially troublesome patents
- ▶ Many valuable uses for this information

Strategic Use of Search Results – cont'd

- ▶ Explore licensing or acquisition opportunities
 - Easier to get good deal early in development
 - Worst time is near commercial launch
- ▶ Develop defensive intellectual property
 - Evaluate and target competitor
 - Provides leverage, opportunity for cross-licensing

Strategic Use of Search Results – cont'd

- ▶ Plan validity attack on troublesome patent
 - Reexamination
 - Interference proceedings
 - Post-grant cancellation proceeding
- ▶ Adjust course of development
- ▶ May inspire further innovations

Strategic Patent Searching Recap

- ▶ Allows for eyes-wide-open approach to patent risks
- ▶ Given advantages and *Seagate*, time is right to implement comprehensive searching program
- ▶ If procedure already exists, revisit and consider expanding and/or improving it

Practical Considerations

- ▶ Enlist patent counsel to help set up searching program
- ▶ Can use technical staff to conduct initial review of results
- ▶ Watch out for privilege and reporting issues
 - Instruct staff on how to properly report findings
 - Take steps to maintain attorney-client privilege

Thank You

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