

Navigating the Patent Minefield

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The Patent Minefield

- Patent infringement suits
 - Costly
 - Risk of preliminary injunction
 - Time consuming
 - Risk of customers being sued
 - Damages
 - Lost profit or reasonable royalty
 - Treble damages and attorney's fees



1. Common Mistakes
2. Ways to Infringe a Patent
3. Minimizing Patent Infringement Risks
4. Being Accused of Infringement

Common Mistakes

- **Our product is covered by our patent(s).**
 - Patents only provide a right to exclude, not a right to practice
 - How about other people's patents?
- **We know our industry very well.**
 - Our product is not the same as the competing product.
 - We know all the patents that covers competitor's products.
- **The patent owner is a small company/an individual and will not sue.**
 - Tenacious in defending patent rights
 - Selling of patent rights
 - Contingency arrangement for infringement suit

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Patent Infringement

- Compare your product to the patent claims
- Direct Infringement
 - Literal Infringement
 - Infringement under Doctrine of Equivalents
- Indirect Infringement
 - Contributory Infringement
 - Infringement by Inducement



US006855334B2

(12) **United States Patent** (10) Patent No.: **US 6,855,334 B2**
 Bhatt et al. (45) Date of Patent: **Feb. 15, 2005**

<p>(54) CONTROLLED DELIVERY OF ACTIVE AGENTS</p> <p>(75) Inventors: Padmanabh Bhatt, Saratoga, CA (US); Evangeline Cruz, Hayward, CA (US); Noyumi Yam, Sunnyvale, CA (US)</p> <p>(73) Assignee: Alta Corporation, Mountain View, CA (US)</p> <p>(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.</p> <p>(21) Appl. No.: 10/001,116</p> <p>(22) Filed: Nov. 27, 2001</p> <p>(65) Prior Publication Data US 2002/0048600 A1 Apr. 25, 2002</p> <p>Related U.S. Application Data</p> <p>(63) Continuation of application No. 09/430,837, filed on Nov. 1, 1999, now Pat. No. 6,368,626.</p> <p>(60) Provisional application No. 60/106,739, filed on Nov. 2, 1998.</p> <p>(51) Int. Cl.⁷ A61K 9/22; A61K 9/24; A61K 9/44</p> <p>(52) U.S. CL. 424/473; 424/468; 424/472; 514/772.3; 514/774; 514/781</p> <p>(58) Field of Search 424/468, 472, 424/473</p> <p>(56) References Cited</p> <p>U.S. PATENT DOCUMENTS</p> <p>2,799,241 A 7/1957 Wurster 3,133,132 A 5/1964 Loeb 3,173,876 A 3/1965 Zobrist 3,276,586 A 10/1966 Rosean 3,541,005 A 11/1970 Strathmann et al. 3,541,006 A 11/1970 Bixler et al. 3,546,142 A 12/1970 Michaels et al.</p>	<p>3,845,770 A 11/1974 Theeuwes et al. 3,865,108 A 2/1975 Hartop 3,916,899 A 11/1975 Theeuwes et al. 4,002,173 A 1/1977 Manning et al. 4,063,064 A 12/1977 Saunders et al. 4,077,407 A 3/1978 Theeuwes et al. 4,088,864 A 5/1978 Theeuwes et al. 4,160,020 A 7/1979 Ayer et al. 4,207,893 A 6/1980 Michaels 4,892,778 A 1/1990 Theeuwes et al. 4,915,949 A 4/1990 Wong et al. 4,931,285 A 6/1990 Edgren et al. 4,940,465 A 7/1990 Theeuwes et al. 5,006,346 A 4/1991 Edgren et al. 5,024,842 A 6/1991 Edgren et al. 5,126,142 A 6/1992 Ayer et al. 5,160,743 A 11/1992 Edgren et al. 5,169,638 A 12/1992 Dennis et al. 5,190,765 A * 3/1993 Jao et al. 424/473 5,252,338 A 10/1993 Jao et al. 5,620,705 A 4/1997 Dong et al. 5,633,011 A 5/1997 Dong et al. 5,600,861 A 8/1997 Jao et al. 6,368,626 B1 * 4/2002 Bhatt et al. 424/473</p> <p>FOREIGN PATENT DOCUMENTS</p> <p>WO WO 95/06460 3/1995</p> <p>OTHER PUBLICATIONS</p> <p>Larry Hixon, et al, <i>Chemical Engineering</i>, 94-103, 1990. ., "Sizing Materials by Crushing and Grinding". (List continued on next page.)</p> <p><i>Primary Examiner</i>—James M. Spear</p> <p>(57) ABSTRACT</p> <p>Controlled release of active agents from sustained release push delivery devices having high drug loading are described wherein residual drug content in the device is minimized by the utilization of a flow-promoting layer between a semi-permeable wall and drug layer comprising the device.</p> <p>7 Claims, 9 Drawing Sheets</p>
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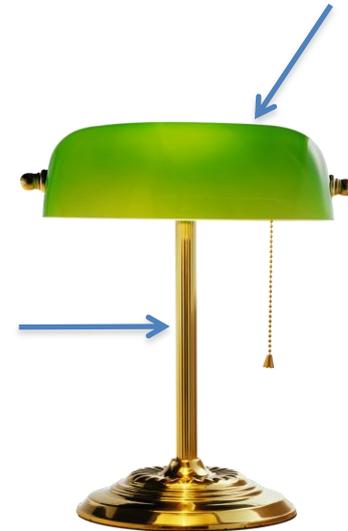


Direct Infringement

- **Literal Infringement**
 - Each claim limitation must be found literally
 - Claim construction may be necessary

Claim 1: A device comprising:

- ✓ element 1;
- ✓ element 2; and
- ✗ element 3.



No literal infringement

Direct Infringement

- Infringement under Doctrine of Equivalents (DOE)
 - Device incorporates a feature that is insubstantially different from the missing limitation
 - Substantially the same function/way/result

Claim 1: A device comprising:

✓ element 1;

✓ element 2; and

✗ element 3.

The device has a feature that is insubstantially different from Element 3



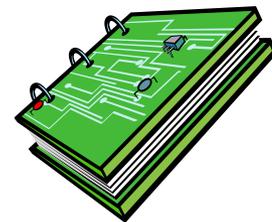
Infringement under DOE

Direct Infringement

- **Doctrine of Equivalents**
 - Slightly expands the scope of the claim as recited
 - **Limitations:**
 - Prosecution history estoppel
 - Cannot cover prior art
- **Must be considered when designing around**

Indirect Infringement

- **Contributory Infringement**
 - Providing a component/material of no substantial non-infringing use
- **Inducement**
 - Knowingly induces infringement with specific intent to infringe
 - User manuals, training materials, videos, web sites, sales pitches, marketing materials



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Survey Competitive Patent Landscape

- Look for freedom to operate or patent clearance obstacles early to avoid pitfalls
 - Identify competitors and their patent claims
 - Work with your patent counsel to understand the patent roadblocks to commercialization
- Delay can be a costly mistake!



It's not just about what you have, it's about what *they* have

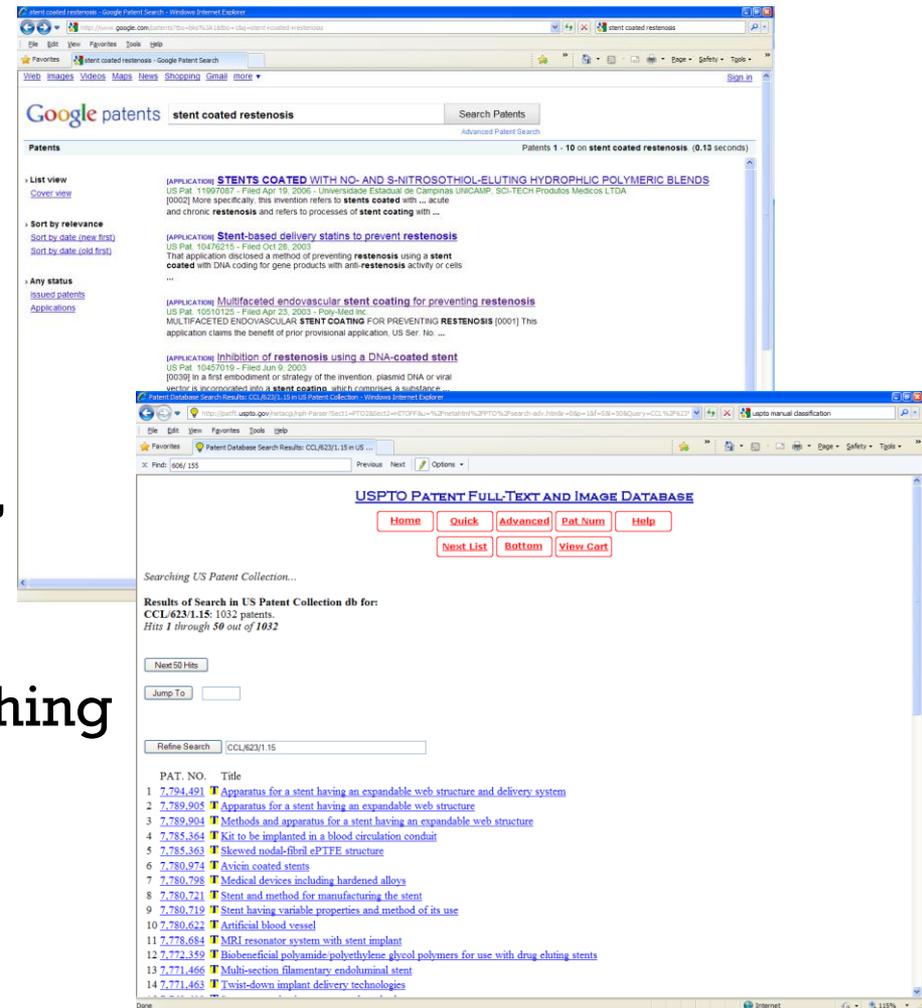
Finding Relevant Patents

- Professional freedom-to-operate searches
- Online patent searches
 - Find patents relating to your product
 - Find patents owned by competitors
 - Find patents of specific inventors
- Examine competitors' products
 - Patent notices on product, packaging, marketing materials or website
 - Obtain patents using the patent notices



Searching DIY

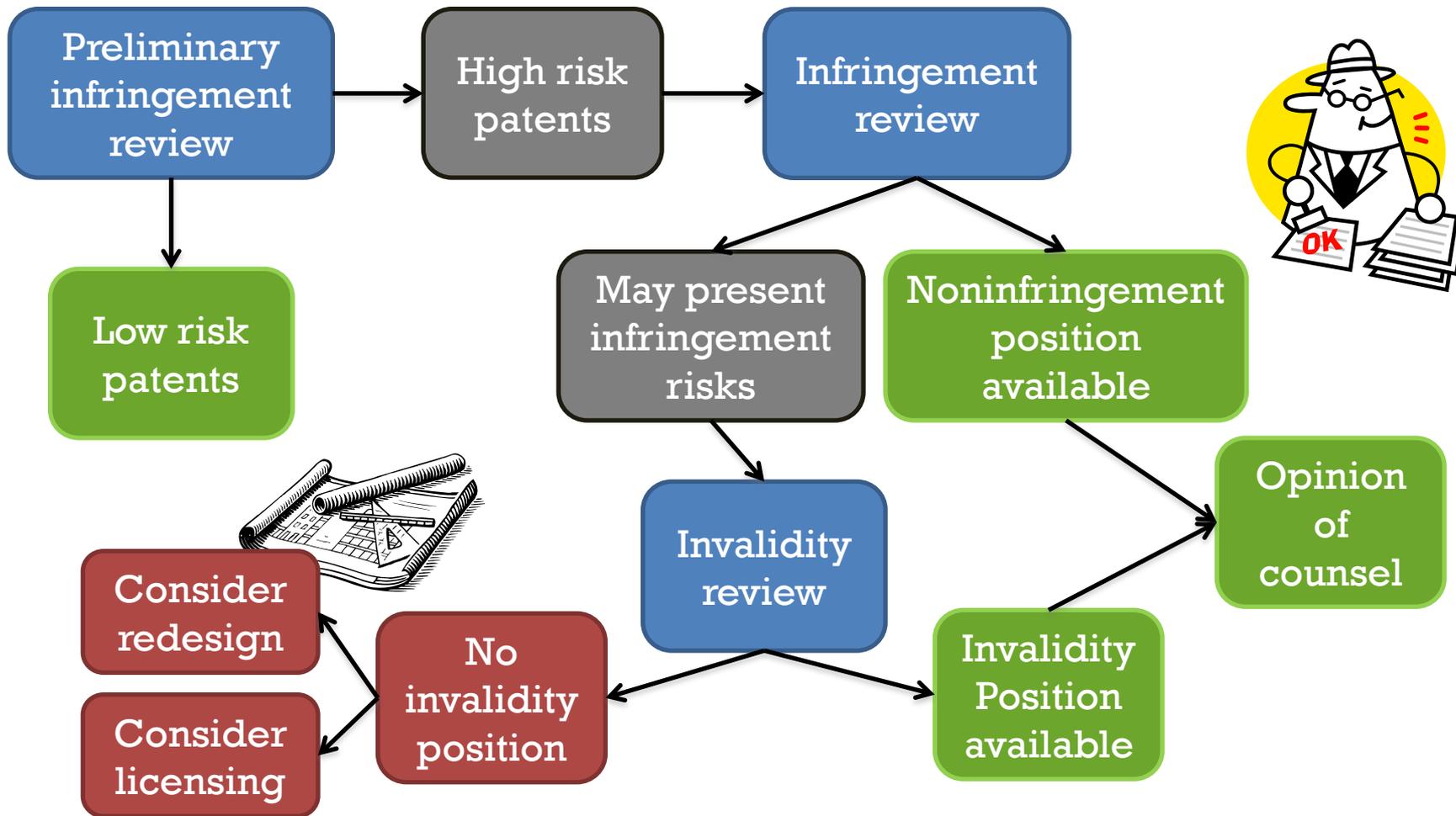
- Key word searching
 - www.google.com/patents
 - patft.uspto.gov
 - www.delphion.com
 - Key words
 - “coated stent restenosis”
 - “drug eluting stent”
- Competitor / assignee searching
 - assignments.uspto.gov



Preliminary Patent Screening

- Patents
 - Is the patent expired?
 - 20 years from the earliest effective filing date (utility patents)
 - www.PatentCalculator.com
 - Are the maintenance fees paid?
 - Preliminary review of patent **claims**
 - Literal Infringement & Doctrine of Equivalents
- Application Publications
 - Monitor the prosecution

Infringement Analysis by Counsel



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Cease & Desist Letter

- Investigate the soundness of the claims of infringement
 - Seek help from your patent counsel
 - Stop the potentially infringing activity if needed
- Respond – honor the deadline
- Seek licensing or design around (watch out for DOE)
- Other options: challenge the patent
 - Requesting the USPTO to cancel claim(s)
 - Ex parte reexamination, inter partes review, post-grant review, covered business methods
 - Declaratory Judgment Action – invalidate the patent

Navigating the Patent Minefield

- **Start your efforts to avoid patent infringement early**
 - Product concept stage: survey the patent landscape
- **Create and maintain your own defensive portfolio**
 - Before starting new R&D project: patentability searches
 - Cross-licensing opportunities
- **Know your competitor's IP as well as your own**
 - Continually gather corporate intelligence
 - Know where you stand in view of competitors
 - Identify potential freedom to operate issues

Don't Operate in a Vacuum

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Orange County



San Diego



San Francisco



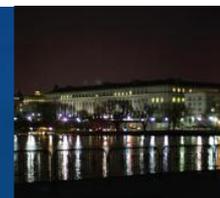
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