

Patent Clearances: How to sell biologic generics and APIs in the USA

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- FDA Approval (required)
- Obtain patent protection (optional)
- Patent infringement clearance (required)
 1. Find relevant patents
 2. Compare patents to our product
 3. Investigate patent invalidity
 4. Challenge patent

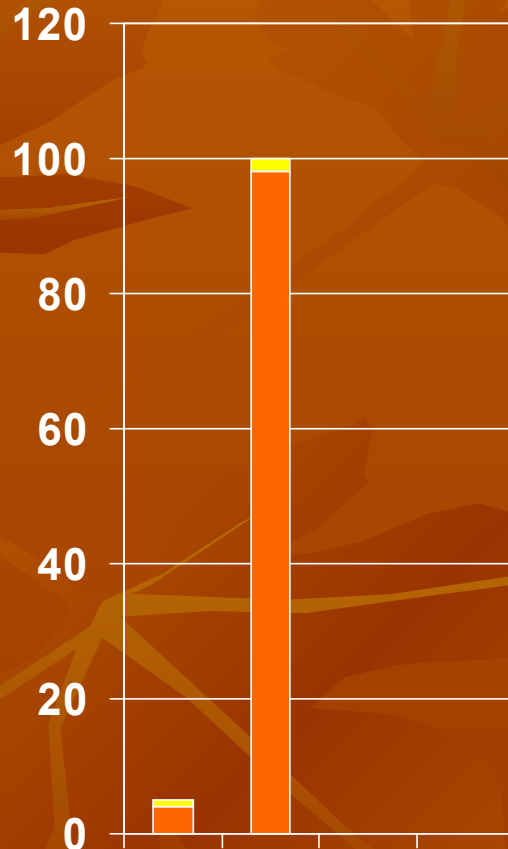
Find relevant patents

- Outside patent firm
- Internal R&D staff
- The Orange Book
 - Not comprehensive
 - Tightened patent listing rules
 - Non-listed patents still dangerous
 - No 30 month stay
 - Injunction against selling (even w/FDA approval)
 - Customs seizure & supply chain issues
 - “Voluntary” injunction

Obtain Patent

- Why do we have patents at all?
- Three requirements for a patent (2-edged sword)
 - Formalities
 - Usefulness
 - Newness
 - Equality
 - Equivalence
- Procedure and investment required

Find relevant patents



“Voluntary” injunction

- Infringement damages = profit
 - Not generic profit
 - Innovator’s lost profit
 - Upside is small; downside is catastrophic
 - Rare to launch before patent is resolved

Find relevant patents

- Challenges
 - proving a negative
 - Misclassified patents
 - Numerous patents for biological products
 - Biotech “restriction” practice
 - Young technology w/foundation patents
 - University, government and unrelated private parties
 - Cf. pharmaceuticals
 - Off-point patents
 - American Rule legal fees
 - Competition law, “objectively baseless” lawsuit
 - Unpublished patents-of-addition

Evaluate infringement

- Protocol
 1. Understand product to be sold
 - *Cf.* changes in product; incomplete information
 2. Read patent
 3. Read prior art of record
 4. Read government correspondence file
 - Define claim terms
 - Discuss how claims are limited *vis* prior art
 5. Provide analysis letter to USA distributor

Evaluate infringement

- Challenges
 - Vague claims - goal of some patent attys
 - Vague Equivalents coverage
 - “Insignificant” [*sic*] difference
 - *E.g.*, same function / way / result
 - Patents of addition with malleable claims

Evaluate Validity

- PTO decision is presumed correct
 - “Clearly” erroneous
 - Based on incomplete information
 - Prior art not of record
 - Resources: outside patent atty; in-house R&D
 - Based on obsolete legal standard
 - Changes in law
 - *E.g.*, Judge Lourie’s “written description” rule (ca. 2000)

Challenge Patent

- Protocol : Paragraph (iii) or (iv) ?
- Evergreening
 - Late-listed Orange Book patents
 - New kind of patent (e.g., metabolite, chiral, purity, blood serum, marketing method (drug registry) patents)

Challenge Patent

- Patent challenge economics
 - *Average* Litigation cost = US\$5,000,000 per party
 - Variable by party
 - Innovator drug profit may justify legal expenses well in excess of US\$5M (*e.g.*, US\$850,000 per month during 1996-97)
 - Out-of-pocket financing occurs before product NOI
 - Pay-for-performance (pay only if you win) requires sharing larger portion of NOI

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* Email newsletter available *