

Medical Device Patents Infringement and Enforcement: Monitoring, Diligence, Alternatives, Path of Enforcement

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1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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February 9, 2021

ENFORCING MEDICAL DEVICE PATENTS

Scott P. McBride
Michael J. Carrozza



McAndrews

AGENDA / CONTENTS

1. Pre-Enforcement Considerations

A. Know Your Goal

B. Risks and How to Minimize Them

C. Know Your Territory

D. Adding to Your Armory

E. To Send, Or Not To Send, a Cease and Desist Letter

2. Enforcement Options

A. District Court

B. International Trade Commission (ITC)

PRE-ENFORCEMENT CONSIDERATIONS

KNOW YOUR GOAL

1. Injunctions
2. Damages
3. Product Change
4. Royalties
5. Licensing Revenue
6. Show of Force

KNOW YOUR GOAL

Injunctions

- Was the norm for infringed U.S. patents
- *eBay Inc. v. MercExchange, LLC*¹
 - SCOTUS: Test for injunctions also applies in patent cases
 - Injunction rates decreased overall
 - Medical device field hit hardest
- **Recent trends**
 - Increasing for all patent cases
 - Now 65% (medical device) vs. 86% (all)

Industry classification and injunction grant rate by industry ²	
Industry sector	Grant rate
Other	90.6%
Chemistry/chemical	88.9%
Pharmaceutical	84.2%
Biotech	83.3%
Consumer goods	81.0%
Transport/logistics	76.4%
Computer/electronics	63.0%
Software	50.0%
Medical devices	46.2%

¹ 547 U.S. 388 (2006).

² Clugston & Kim, *The Unintended Consequences of the Injunction Law after eBay v. MercExchange: An Empirical Study of the Effects on Injunctions in Patent Law*, 99 J. Pat. & Trademark Off. Soc'y at 249, 258 (2017).

KNOW YOUR GOAL

Damages

- Generally, high profit margins for medical devices
- Patent infringement awards can thus be lucrative
- Damages floor in 35 U.S.C. § 284:
 - “adequate to compensate for the infringement, but in no event less than a reasonable royalty”
 - Amount hypothetical infringer would have paid
- Judicial restrictions:
 - Apportionment of damages to actual contribution of patented invention

KNOW YOUR GOAL

Product Change

- Accused infringer may settle dispute by agreeing to make and sell modified, non-infringing product
- Can be valuable if modified product is competitively inferior
- Other barriers to entry in medical device space:
 - Significant resources to redesign product?
 - Regulatory clearance or approval may delay re-entry into market

KNOW YOUR GOAL

Royalties

- Accused infringer may settle dispute by taking a license & paying royalties
- Potential benefit to patent owner:
 - Effectively, enlarged market share—revenue from competitor products
- Ongoing royalty may be awarded in place of injunction
 - Requires some level of consent because not set forth in Patent Act

KNOW YOUR GOAL

Licensing Revenue

- Benefits of enforcement campaign can extend beyond injunctive relief or damages
- Mere presence of patent infringement lawsuit can encourage some medical device manufacturers to pay royalty
 - Accused infringer can avoid risks, costs, and uncertainty of litigation
- Domino Effect: As more companies take license, others become interested

Show of Force

- Successful enforcement campaign can prompt companies to avoid patented technology
- Fear of being next accused infringer

RISKS AND HOW TO MINIMIZE THEM

Retaliatory Risks

- Accused infringers typically assert their own patents against plaintiff's products
- Puts products, market share, and revenue at risk
 - Could jeopardize products unrelated to original litigation
- Costs can quickly double or more
- Plaintiff becomes an accused infringer—potentially liable for damages and enjoined from making and selling products

RISKS AND HOW TO MINIMIZE THEM

Suggestions to Minimize Retaliatory Risks

- Conduct due diligence on competitor's patent portfolio to:
 - Identify patents competitor most likely to assert against **products at issue**
 - Conduct global patent searches
 - Map out competitor's patent coverage by jurisdiction
 - Determine how coverage overlaps with plaintiff's current and future business plans
 - Identify patents competitor can potentially assert against **unrelated products**
 - Accused infringer may counterclaim to disrupt different market segment
 - May seek leverage to force a settlement

RISKS AND HOW TO MINIMIZE THEM

Suggestions to Minimize Retaliatory Risks

- Commence efforts to mitigate risks
 - Examine competitor's most dangerous patents for non-infringement and invalidity
 - Conduct prior art searches to invalidate competitor's patents
 - Obtain opinion(s) of counsel where appropriate
 - Explore potential design-arounds with R&D (and marketing)

RISKS AND HOW TO MINIMIZE THEM

Risks Associated with Patent Challenges

- Risks from enforcement campaign can extend beyond case itself
- If patent(s) declared invalid, can:
 - nullify existing license agreements and royalty streams; and
 - eliminate barriers to entry for all parties, not just accused infringer.

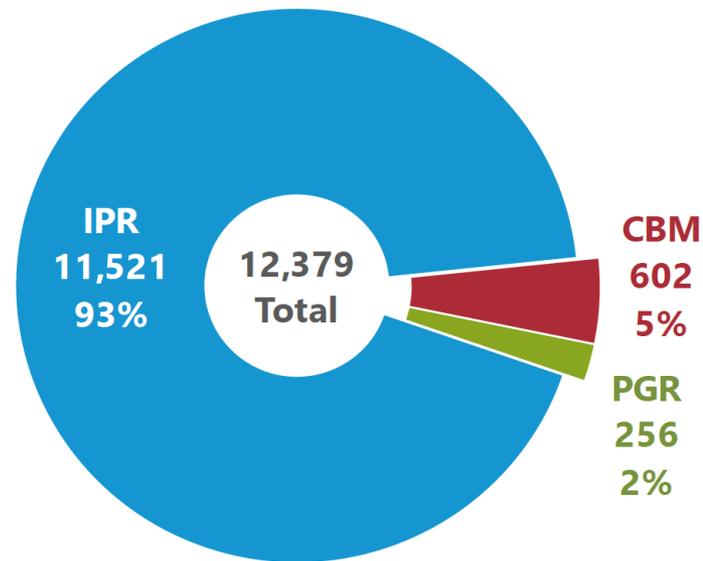
RISKS AND HOW TO MINIMIZE THEM

Risks Associated with Patent Challenges

- In 2012, Congress enacted new vehicles to challenge patent validity
- Proceedings conducted by Patent Trial and Appeal Board (PTAB)
- **Post-Grant Review (PGR)**
 - Comparable to European oppositions
 - Petition must be filed within 9 months of issuance
 - Challenges based on any patentability or eligibility ground
- ***Inter Partes* Review (IPR)**
 - Petition can be filed any time during life of a patent (but within 1 year of being served a complaint)
 - Challenges based only on printed publications (e.g., patent and non-patent literature)

RISKS AND HOW TO MINIMIZE THEM

Petitions by Trial Type³ (All Time: Sept. 16, 2012 to Nov. 30, 2020)

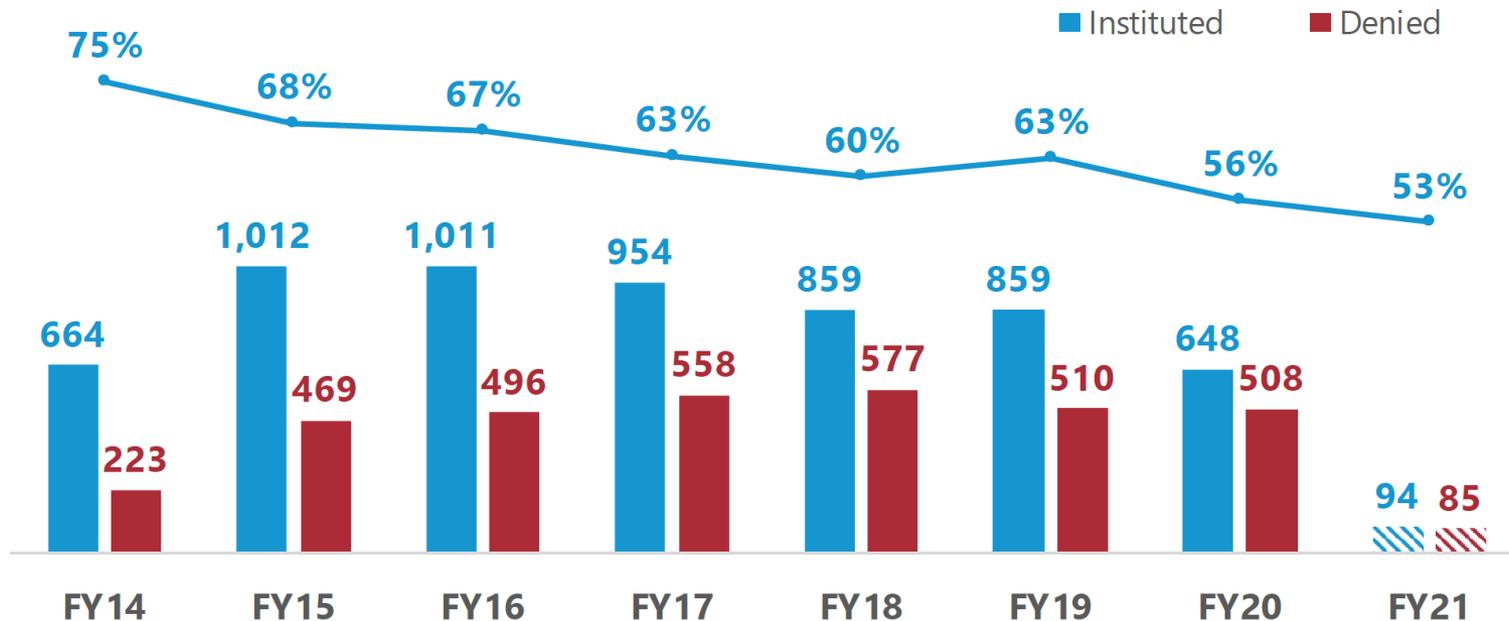


³ Trial Statistics: IPR, PGR, CBM, Patent Trial & Appeal Board (Nov. 2020).

RISKS AND HOW TO MINIMIZE THEM

Institution Rates⁴

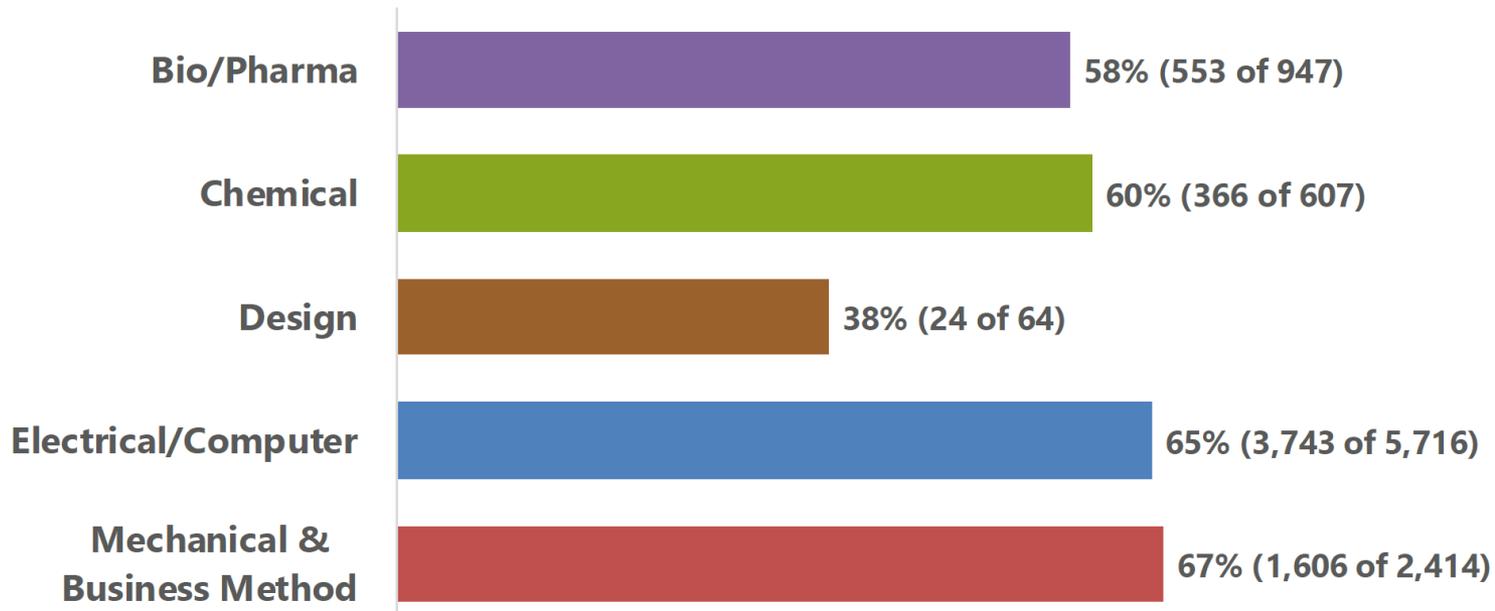
(FY14 to FY21: Oct. 1, 2013 to Nov. 30, 2020)



⁴ Trial Statistics: IPR, PGR, CBM, Patent Trial & Appeal Board (Nov. 2020).

RISKS AND HOW TO MINIMIZE THEM

Institution Rates by Technology⁵ (All Time: Sept. 16, 2012 to Nov. 30, 2020)



⁵ Trial Statistics: IPR, PGR, CBM, Patent Trial & Appeal Board (Nov. 2020).

RISKS AND HOW TO MINIMIZE THEM

Suggestions to Minimize Risks Associated with Patent Challenges

- Identify most problematic prior art
- Carefully select which patents and claims to assert to avoid that art
- Interview inventors to learn about impetus for invention
- Conduct early review of documents relating to:
 - Conception and reduction to practice; and
 - Favorable and unfavorable evidence.
- Patent enforcement most successful when accompanied by a compelling story

KNOW YOUR TERRITORY

Geographical considerations

- Patents are enforceable in country or region where granted
- Need to select in which jurisdiction(s) to enforce
- Need to understand where a counterattack may occur

KNOW YOUR TERRITORY

Investigate the following:

- In which jurisdictions do the parties make and sell the accused products?
- In which jurisdictions have the parties sought or received regulatory approval?
- In which jurisdictions, and to what extent, do the parties hold market share unrelated to, or collateral to, the subject products?
- In which jurisdictions do the parties have patent coverage?
 - Engage foreign counsel, where appropriate

ADDING TO YOUR ARMORY

Maintaining patent coverage

- Often overlooked as part of an enforcement strategy
- Can provide versatility and leverage
- If patent disclosure is broad, may be able to procure additional patent claims during enforcement campaign that cover competitor's new features or design-arounds
- Sends a strong message to competitor: "Even if you escape liability here, there are more patents to follow."

ADDING TO YOUR ARMORY

Suggestions for maintaining patent coverage

- **Track One – prioritized examination program with USPTO**
 - Can request Track One status when filing application or RCE
 - Limited to 12,000 applications per year (as of Sept. 2019)
 - Fee is \$4,000 (small entity is \$2,000)
 - If granted, application is given special status with fewer requirements
 - Goal: To reach a final disposition on application within 1 year
 - Often times much quicker (e.g., 3-6 months from filing to allowance)
 - Can lose Track One status for variety of reasons
 - E.g., Petition for extension of time for reply; claims amended to more than 4 independent claims or 30 total claim; RCE filed; notice of appeal; NOA mailed; final office action mailed

ADDING TO YOUR ARMORY

Suggestions for maintaining patent coverage

- **Informal means to expedite patent prosecution**
 - Quick response to office actions
 - Examiner interviews
 - “Super claims”—many claim limitations to avoid prior art, but drafted to cover a competitor’s product

TO SEND, OR NOT TO SEND, A C&D LETTER

Reasons to send cease and desist letter:

- Put accused infringer on notice of infringement to start damages clock
- Earnest attempt to stop infringement without litigation
- Factor when seeking enhanced damages for willful infringement
- To “flex your muscles”

Reasons not to send cease and desist letter:

- Can create grounds for declaratory judgment action
- Prompts accused infringer to begin planning defensive strategies
- Potentially creates protracted letter campaign—accused infringer may not have any real desire to cooperate

TO SEND, OR NOT TO SEND, A C&D LETTER

The fine line between a case or controversy, or not

- “[W]hether the facts alleged, *under all the circumstances*, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”⁶
- Language of cease and desist letter matters
- Trying to avoid DJ jurisdiction with **hints of infringement** often backfire
 - May not trigger damages clock while also alerting accused infringer
- Unequivocally asserting infringement will start damages clock, but may prompt accused infringer to file DJ action in choice of venue

⁶ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

TO SEND, OR NOT TO SEND, A C&D LETTER

Suggestions to thwart race to the courthouse

- File, but do not serve, lawsuit in plaintiff's choice of venue
 - 90 days to serve under the Federal Rules
- Send cease & desist letter to accused infringer
- If DJ lawsuit filed in different jurisdiction, move to transfer to jurisdiction where plaintiff filed first

ENFORCEMENT OPTIONS

DISTRICT COURT

Numerous factors to consider

- Personal jurisdiction
- Venue
- Patent-specific factors
 - Local patent rules
 - Volume of patent cases heard
 - Pro-plaintiff vs. pro-defendant
 - Grant rate of motions (e.g., dispositive motions, stay pending IPR, etc.)
 - Likelihood of injunctive relief
 - Home turf of either party
 - Median time to trial

DISTRICT COURT

Personal Jurisdiction

- General jurisdiction
 - State where party can be used for any claim
- Special jurisdiction
 - State in which accused infringer has “purposely availed itself” (e.g., selling products on regular basis)
- Will likely reduce the pool of 94 potential district courts

DISTRICT COURT

Venue

- Proper in the judicial district where the defendant
 - (i) resides or
 - (ii) has committed acts of infringement and has a regular and established place of business⁷
- Supreme Court’s *TC Heartland* decision severely restricted “forum shopping”
- Significantly limits venue—often satisfied by only a few potential courts

⁷ See 28 U.S.C. § 1400(b); *TC Heartland LLC v. Kraft Foods Grp. Brands, LLC*, 137 S. Ct. 1514 (2017).

DISTRICT COURT

Patent Specific Factors

- **Local Patent Rules**

- Procedural rules proscribed by court to streamline patent cases
- Mandatory “contentions” intended to take the place of interrogatories

- **Volume of Patent Cases Heard**

- Judges well-versed in patent law may be preferable

- **Pro-plaintiff v. Pro-defendant**

- Some courts are known to be more “friendly” towards certain types of parties

- **Grant Rate for Motion Practice**

- E.g., Dispositive motions and motions to stay pending IPR
- Some courts willing to stay merely on petition for IPR being filed

DISTRICT COURT

Patent Specific Factors

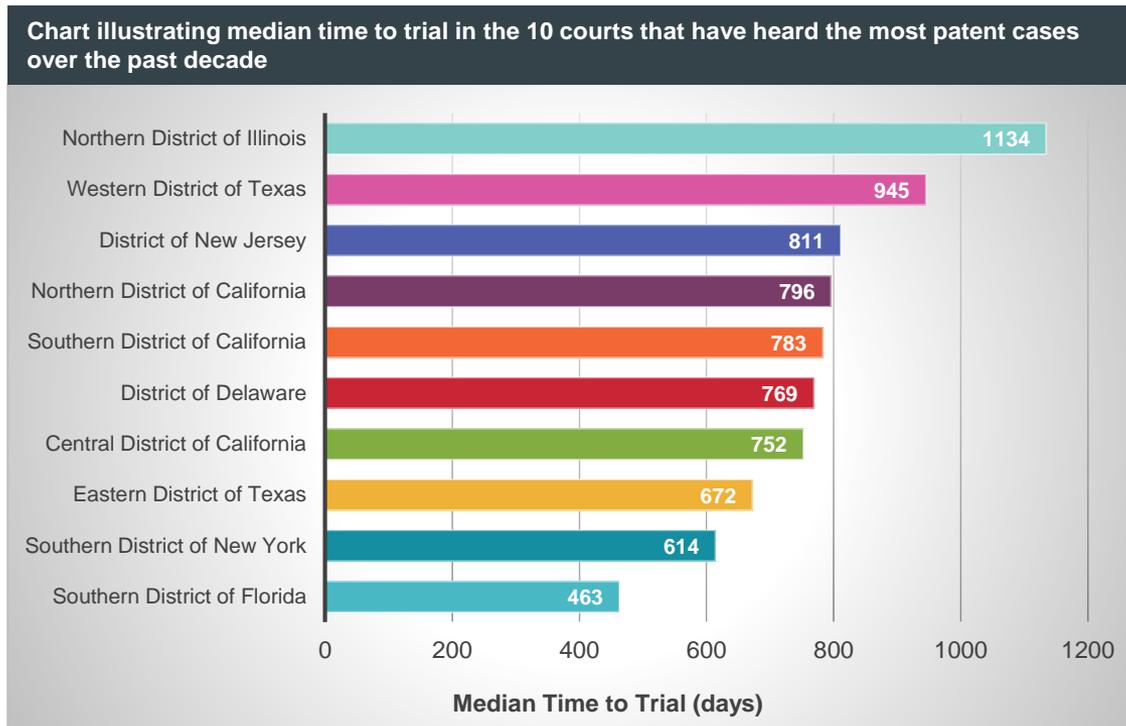
- **Grant Rate for Motion Practice**
 - Dispositive motions and motions to stay pending IPR
 - Some courts willing to stay merely when petition for IPR is filed
 - Accused infringers typically push for a stay to save litigation costs
 - Plaintiffs typically oppose a stay to keep pressure on accused infringer
- **Likelihood of Injunctive relief**
 - Injunctive relief for medical device cases on the rise
 - Approximately 65% for medical device cases vs. 86% for all other cases
- **“Home Turf”**
 - Parties always seek venue where jurors may be loyal

DISTRICT COURT

Patent Specific Factors

- Median Time to Trial

- Some courts boast “rocket dockets”; others are notorious for slow dockets



INTERNATIONAL TRADE COMMISSION (ITC)

Alternative to district court

- Enforcement actions protect against “unfair competition”
- Protect an established industry or a developing one
- Decision makers: administrative law judges and commissioners of ITC
- Conducts trials on patent infringement
- Most common remedy is an exclusion order (similar to injunction)
- Money damages not available
- Attractive option when competitor manufactures outside U.S. and imports for sale
- Speedy proceeding—typically 17 months to complete (statutory deadlines)

THANK YOU

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