

# IP Infringement Enforcement Strategies

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# The Facts

- IAMIT is a multinational pharmaceutical and manufacturing company with patent and trade-mark registrations covering the its drug and product offerings in China, the European Union, the United States and Canada.
- In addition to its key blockbuster drug which the generics are trying to duplicate, IAMIT also has to contend with counterfeiters targeting IAMIT's world leading brand of e-cigarettes using the PUFFALOT registered trade-mark.

# Pre-Litigation Considerations China



- Forum shopping possible and important
- check the validity of your IPR
  - patent: stable?
  - TM: continuous use?
- what is the key goal of your action?
- negotiation/warning letter go first?
- Consider declaratory judgment litigation available in China
- laches: 2-year time limit
- case evaluation: chance to win? chance to get damage? cost estimation?
- litigation strategy: target choice; jurisdiction choice
- any alternative solution?

# Pre-Litigation Considerations

## EU



- Trade-mark
  - EU system established in 1994; in force from 1996
  - [Old system: national trade-marks]
- Patents
  - New system: Unified Patent Court (UPC; for EPs and Unitary Patents (UPs); in force from 20XX
  - [Old system: national patents and EPs (before 20XX)]

# Pre-Litigation Considerations

## EU



- Trade-mark (EU)
  - Validity: Continuous use, includes territorial scope of use
  - TM identity/similarity
  - Movement of infringing goods: import and transit; advertisements, etc.
  - Forum
- Patents (EPs and UPs)
  - Validity: EPC (decision practice of EPO and national decision practice)
  - Market authorisations
  - Timelines (incl. preliminary proceedings)
  - Forum

# Pre-Litigation Considerations United States



- Preparation begins during patent prosecution
  - Assumption is that all products will be litigated (Hatch-Waxman provides incentive to do so)
- Quality reviews of patent prosecution in key countries
- Hatch-Waxman- begins with notice to innovator company
- Initiation of litigation within 45 days leads to withholding of approval of generic application for up to 30 months
- First ANDA filer, if they succeed, gets 180 days as the only approved generic, which is highly profitable
- America Invents Act has added challenges, since later filers can choose this route, albeit they do not get the 180 semi-exclusivity

# Pre-Litigation Considerations Canada



- Plaintiff should ensure that IP registrations are in order to avoid unnecessary challenges and costs.
- Cease and desist letter; it may avoid the need to seek an injunction.
- No wilful infringement issues for possible treble damages but possible punitive damages.
- Acquire and assess samples of the infringing items.
- Defendant should investigate IP coverage before launching.
- PM NOC Regulation proceeding issues.
- Be mindful of timing constraints.

# Investigations-China



## Investigation means

1. Watch/investigation by own salesman/IP staff
2. IP lawyer investigation
3. Professional investigation company
4. Evidence collection by court (when applicable)
5. Customs action + court (where applicable)
6. Oversea investigation (e.g., *saisie-contrefaçon* (search order to preserve evidence) in France)

# Investigations-EU



- EU Enforcement Directive (EU-DI 2004/48/EC)
  - Securing evidence
  - Provisional and precautionary measures
- EU Customs Regulation for IPRs (EU-RE 608/2013)
  - Counterfeit or pirated goods
  - Transit
- UPC Agreement (UPC-A)
  - Order to produce evidence and to inspect premises; incl. physical seizure
  - Court experts

# Investigations – U.S.



- In Hatch Waxman process, ANDA applicant needs to specify reasons for non-infringement or invalidity
- Sometimes further correspondence needed to clarify positions
- No product on sale in US
- May know about product from sales outside US
- Counterfeit products provide for lots of cooperation with authorities to share information and ameliorate the health risks to the public

# Investigations - Canada



- If obtaining a sample of the suspected infringing item is impractical, a motion to inspect at the defendant's place of business may provide the evidence.
- For counterfeit products, consider whether an Anton Piller order is appropriate (i.e., is there a danger of the evidence disappearing).
- Consider using a forensic company to do prepare a report.



# Court Selection and Venue - EU



- Community trade mark (CTM) courts (TM infringement and counterclaim for invalidity)
- OHIM Cancellation Divisions (TM revocation and invalidity)
- Local, Regional or Central Division (EP/UP infringement and counterclaim for invalidity)
- Central Division (EP/UP invalidity)

# Court Selection and Venue – U.S.



- Exclusive jurisdiction in Federal District Court
- In ANDA cases, can sue in home Federal District Court (see, e.g., ELI LILLY AND COMPANY et al v. ACCORD HEALTHCARE INC., USA; Acorda Therapeutics, Inc. v. Mylan Pharamceuticals Inc., 2015 WL 186833 (D. Del. Jan. 14, 2015) and AstraZeneca AB v. Mylan Pharmaceuticals, Inc., WL 5778016 (D. Del. Nov 5, 2014))
- Many are filed in Delaware, as many pharma companies are Delaware corporations
- Globally, always better to avoid defendant's home venue

# Court Selection and Venue - Canada



- Superior Courts of Justice for the various Provinces and Territories and the Federal Court of Canada have concurrent jurisdiction to deal with patent and trade-mark infringement.
- No juries in the Federal Court.
- The Federal Court has exclusive jurisdiction to deal with invalidity and expungement issues and its orders are enforceable throughout Canada at first instance.

# Administrative Proceedings - China



## Local IP Office action for patent

1. Applicable for patent (invention, utility model and design)
2. Prima facie infringement evidence is sufficient to start the action
3. No damage

## AIC action for TM

1. Applicable for TM infringement
2. Quick
3. Prima facie infringement evidence is sufficient to start the action
4. Powerful investigation
5. No damage

## border measures- customs action for both patent and TM

1. Applicable for import/export of infringing products
2. beneficial to record IPR at customs
3. seizure of goods (ex-officio or upon requested)

# Administrative Proceedings - EU



- Customs
- OHIM
  - TM registration
  - TM revocation and invalidity
  - Appeals
- EPO
  - EP/UP examination and grant; opposition
  - Appeals
  - UP administration (appeals: UPC)

# Administrative Proceedings – U.S.



- ITC is a good option for certain types of products that are consumer driven (e.g., drugs for erectile dysfunction) since they are sold over the internet
- ITC order can help to shut down web sites
- *In rem* orders sometimes hard to enforce, due to fact shipments are in small quantities, with no identifying label
- Trademark infringements are easier to enforce than patents
- Post grant proceedings in the US after the AIA are becoming more common, even for pharma cases

# Administrative Proceedings - Canada



- No administrative body like the U.S. ITC
- Canadian Border/customs orders are hard to enforce in patent infringement cases.
- For trade-marks, the *Combating Counterfeit Products Act* enables Canada Border Services Agency officers to detain suspected infringing goods and allows them to share information with IP owners who have filed a "Request for Assistance".

# Experts - China



- Experts are commonly used in IP litigation, especially in patent litigation.
- Role of experts: kind of witness, to be cross-examined.
- Types of experts:
  - (1) expert witness invited by one party;
  - (2) expert witness recommended by court;
  - (3) expert witness invited by court;
  - (4) Technical appraisal experts agreed by both parties.

## **Technical researchers in IP courts:**

*Function:* to assist judges with technical issues by conducting technical research and analysis and providing technical opinions to judges

# Experts - EU



- OHIM
  - Opinions by experts = evidence (oral evidence possible, if required by OHIM)
- CTM courts
  - Practice depends on the CTM court
- EPO
  - Opinions by experts = evidence (oral evidence possible, if required by EPO)
- UPC
  - (technical judges)
  - Court experts
  - Experts of the parties (= evidence; incl. oral evidence)

# Experts – U.S.



- Try to get experts early, someone who is well known, yet independent
- Often use same expert in several countries
- Will be subjected to thorough cross exam in depositions and sometimes at trial
- All prior writings and presentations will be reviewed

# Experts - Canada



- Whether in the Federal or Provincial Superior Courts of Justice, testifying experts (as opposed to consulting experts) must acknowledge their independence and can only testify with respect to prior delivered reports.
- The Ontario Court of Appeal recently confirmed that counsel may assist the testifying expert in preparing their reports.
- Securing experts at the earliest possible time is a good practice to avoid last minute conflicts and/or rushes.

# No Discovery available in China



## Proving your case

**basic rule**: who claims, who proves!

***exception***: method patent for manufacturing a new product

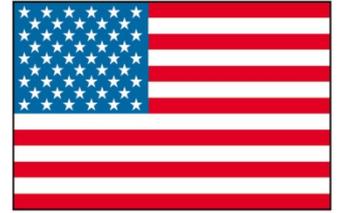
- Hard to collect evidence and need a good strategy;
- formality requirement for evidence is strict: notarization is commonly used for evidence collection; evidence formed out of China required notarization and legalization; foreign language required to be translated into Chinese
- the defendant does not have the liability to disclose information unless requested by the court or other authority.

# Discovery - EU



- Securing evidence possible (as the last piece in the – otherwise well documented – chain of evidence)
- No US style discovery
- Securing evidence without hearing the other party
- EU Enforcement Directive
- UPC Agreement

# Discovery – U.S.



- This is the most expensive part of US litigation
- Good document management is key
- Courts and magistrates often err of the side of providing access to more documents
- Plaintiff company (patent holder) is always going to have lots more documents than defendant
- Selection of a knowledgeable person to answer for the company (Federal Rule 30(b)(6)) is often very important

# Discovery - Canada



- The discovery of persons in Canada is more limited than the U.S. deposition process.
- Typically, examination is limited to one representative of the party who must inform themselves of the facts relating to the issues.
- In patent cases, the inventor(s) can also be examined in addition to a representative of the plaintiff.
- Examination of non-parties is available in limited circumstances.
- Don't underestimate the usefulness of documentary discovery.

# Document Management/Retention China



- it is not a crucial matter in China.
- however, for patent, doctrine of estoppel is adopted in infringement litigation. It is important to check the prosecution history of the concerned patent before litigation.

# Document Management/Retention EU



- Scope of EP/UP:
  - Art. 69 EPC
  - [National law(s) and practice(s)]
  - Autonomous UPC interpretation?
- No US style file wrapper estoppel
- Privilege

# Document Management/ Retention U.S.



- Broad discovery available, important to have and strictly adhere to document retention guidelines
- E-Discovery is generally largest
- Privileged documents in US include advice from in-house and outside patent attorneys
- Issues regarding global litigation and privilege accorded
  - Documents might be excluded in US, available in another country
- Keep only documents for which there is a business need
- Must implement well in advance of litigation
- Need to have policies regarding litigation holds for litigation

# Document Management/Retention Canada



- Be prepared for e-discovery – breadth and cost.
- Translation issues – another cost sink.
- Spoilation concerns – the duty to preserve.
- Collection of the relevant documents and appointment of a client point-person.
- Privilege issues (solicitor advice and litigation privilege).
- Protective orders – are they necessary?
- For patents, no file wrapper estoppel in Canada.

# Witnesses -China



- Witness is rarely used in IPR litigation cases, except the technical experts.
- Witness needs to present at the hearing and to be cross examined; however, it happens often that only written statement by witness is written during the hearing.
- material subjects and documentary evidence normally have higher credits than witness.

# Witnesses - EU



- EPO/OHIM
  - Possible, usually not important in most cases
- UPC/CTM court
  - May be very important
  - Translation can be crucial issue (direct impression for court?)

# Witnesses U.S.



- Assemble list of probable witnesses including inventor(s), experts
- Will likely be deposed and then become witness at trial
- Need to prepare fully

# Witnesses - Canada



- Determine who the necessary witnesses are and obtain signed statements as early as practicable.
- Is translation an issue? If so, source interpreters for interviews, discovery and trial as early as possible.
- Maintain contact up to and including trial.

# Interlocutory Remedies China



- **evidence preservation** may be requested with the court to help collect evidence.
- **property preservation** procedure can be used to guarantee the enforcement of damage judgment.
- **preliminary injunction** possible but very hard to get.
- **permanent injunction** to be granted almost in all cases with exceptions for public interests consideration.
- **damage compensation** still low in most cases due to the difficulty of proving.



# Interlocutory Remedies -EU

- Available for TM and EP/UP infringement
- Available for securing evidence
- Must be well-reasoned
- Without hearing the other party?
  - Possible, but rare for injunction
  - Possible for securing evidence

# Interlocutory Remedies – U.S.



- In general in US, preliminary injunctions in patent cases for patents that have not been litigated before are difficult to obtain- key is likelihood of success on merits
- However, in pharma cases, irreparable harm is likely from introduction of generic product prior to patent expiration
- Hatch-Waxman provides a way to litigate patent issues prior to generic drug approval
- Withholding of generic approval is in lieu of getting an injunction

# Interlocutory Remedies - Canada



- Equitable relief is discretionary and the maxims apply.
- Consideration of possible injunctive relief (*ex parte*, *interim* and permanent).
- Anton Piller orders to seize evidence.
- Mareva injunctions to prevent dissipation of assets.

# Cost Containment/Budgets China



- Litigation in China is quick and inexpensive.
- The plaintiff does not have the risk to bear any cost of the defendant even if it loses, unless it is a bad faith litigation.
- The plaintiff may be compensated from the defendant for the reasonable disbursement but in rare cases it may be awarded with attorney fee or only very little if he does.
- In most of the cases, the damage is decided by the judges' discretion within statutory damage range.

# Cost Containment/Budgets

## EU



- OHIM
  - Unsuccessful party pays, however... (TM-RE)
- EPO
  - Each party bears its costs, unless ... (EPC)
- CTM Court
  - Unsuccessful party pays (Enf.-DI)
  - It depends
- UPC
  - Unsuccessful party pays (UPC-A)
  - It will depend

# Cost Containment/Budgets U.S.



- US patent litigation is very expensive, generally due to extensive discovery
- Appropriate document retention is one means of controlling costs
- Alternate means of complying with document requests, using third parties for document management and translations can also help to reduce costs
- Firms are requested to provide budgets for every lawsuit

# Cost Containment/Budgets Canada



- Litigation is expensive and not easily priced, especially for one-off mandates yet cost containment, alternate fee arrangements and budgets are the new reality.
- Infringement/invalidity proceedings are especially difficult to cost contain/predict because of the variables.
- Legal costs and disbursements are awarded to the winning party and are impacted by Offers to Settle.