Litigation and regulatory strategies involving IP rights

Sham Litigation

Regulatory abuses (briefly)

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Use and abuse of the IP and regulatory system

- The use and abuse of the IP and regulatory system by corporations with the aim to maintain or extend their market power and to exclude competitors may take different forms
  - (i) a **collusive conduct**, relating to patent litigation settlements between brand name and generic drug manufacturers involving so called “reverse payments”
  - (ii) **unilateral practices** by dominant firms which by abusing the regulatory and litigation system aim to raise the costs of their competitors and exclude competition
- , the abuse may take the form of a ***fraudulent litigation*** or some form of misrepresentation in the context of the regulatory process
- It might also consist in instigating litigation with the collateral purpose of inflicting an anticompetitive injury. In the context of patent litigation, the conduct takes the form of competition law (antitrust) counterclaims to patent infringement suits (***vexatious litigation, sham litigation***)
  - “the use (of) the governmental process as opposed to the outcome of that process as an anticompetitive weapon” *City of Columbia v. Omni Outdoor Advertising*, 499 U.S. 365 (1991):

The rise of IP litigation

- Use and abuse of regulatory/litigation procedures as a competition law infringement

– EC Pharmaceutical sector inquiry (2008), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/exec_summary_en.pdf

- The average duration of opposition and appeal proceedings averages 2,8 years (from 6 months to 6 years in some Member States)
- Litigated infringement proceedings could take about 7 years
- The average duration of interim injunctions granted was 18 months
- Litigation costs are important (for generics) as they face multiple actions in multiple states, given the absence of a unified EU patent system
- UPC (2017)

Public or Private Restraint?

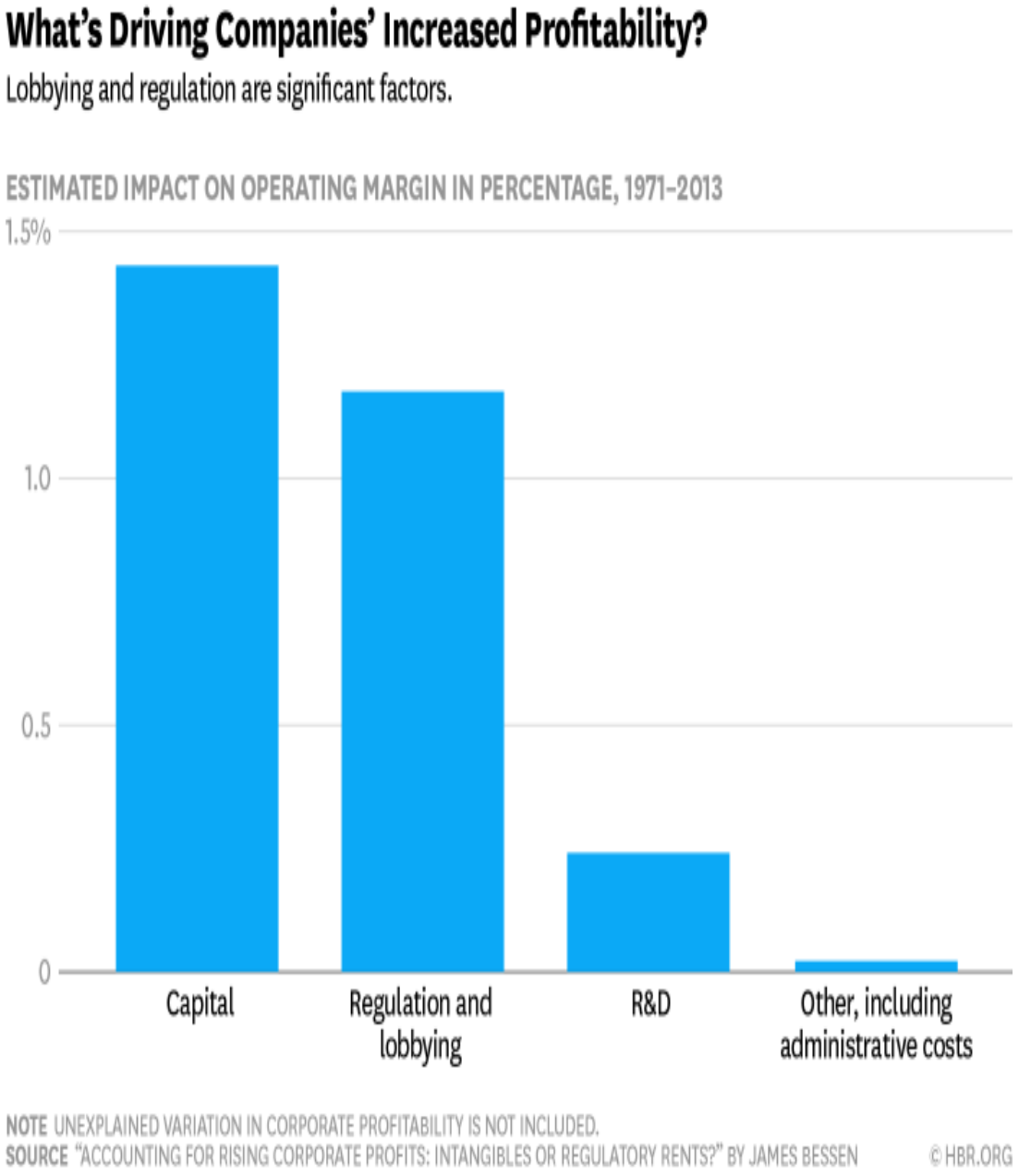
•A common characteristic of this type of cases is that it encompasses situations in which ***undertakings use the governmental process as an anticompetitive weapon***.

•Private decision-making: not immune from competition law

•Public decision-making: in principle, immune from competition law (US) with some exceptions

•Higher aggregate profits in the "rent-seeking sector": pharma/chemicals, petroleum refining, transportation equipment/defense, utilities, communication (Bessen, 2016)

- •For each dollar spent lobbying for a tax break, firms received returns in excess of $220



Use and abuse of the IP and regulatory system

- A common characteristic of this type of cases is that it encompasses situations in which ***undertakings use the governmental process as an anticompetitive weapon***.
- Einer Elhauge: there are two poles to take into account: from one side, the private decision-making process, which is not immune from the application of competition law; from the other, the public decision-making, which is in principle immune from competition law, with the exception of situations where a financially interested decision-maker controls the terms of the imposed restraints to competition
- It follows that petitioning a financially disinterested government actor, through the normal means of the relevant political or procedural process, does not constitute a restriction of competition, even if the petitioning is done by a financially interested private actor, as it is assumed that the normal governmental process and an accountable governmental actor will represent all the affected parties and will decide according to the public interest

Immunizing anticompetitive conduct in order to preserve other (constitutional) values

- Certain conduct has been granted immunity from competition law liability, regardless of the extent of anticompetitive effects
- Political process: *Noerr Pennington* doctrine and immunity from antitrust
  - 1st amendment US Constitution, prevening Congress from abridging "the right of the people… to petition the government for a redress of grievances"
  - Article 227 TFEU (right of petition to the European Parliament)
- Adjudicative process: immunity is narrower (*California Motor*)
  - what constitutes a restriction of competition is not the process itself but the ***abuse of process*** (in this case litigation). The restriction of competition flows directly from a "private" action, as the injury would have happened no matter what the government official would have decided. The situation should thus be distinguished from that where a disinterested accountable decision-maker makes a substantive decision in favour of the restriction to competition.
- Litigation process
  - Access to the court

Limiting patent “trolls”

- Non-practising entities that do not develop technologies but whose business model is to generate revenues by asserting their patents or those of third parties
- Sometimes hybrids: acquire patents from operating companies and maintain a relation with these companies post-acquisition
- Lottery tickets trolls
- Bottom feeders trolls
- 2/3 of patent cases in the US are now brought by patent trolls
- Number of defendants in patent troll lawsuits increased six fold from 2003 to 2013
- 89% of increase in patent litigation to software patents
- Business method patents constitute 10% of the patents used in lawsuits by NPE (including patent trolls)
- Cost to US startups: more than $20 billion in VC investment

- Not such a problem in Europe: fewer software patents and “loser pays” litigation costs (in the UK)

Use and abuse of the IP and regulatory system

One could distinguish two different exceptions to the antitrust immunity from which benefit litigation/regulatory strategies:

(i) the ***sham litigation exception*** and

(ii) ***litigation based on a regulatory fraud or misconduct***

Sham litigation

The sham litigation exception

- Frivolous litigation has detrimental effects beyond the litigants involved (suppliers, distributors, purchasers)

- A subjective test would focus on the ***intent of the litigant***: litigation would be found sham merely because a subjective expectation of success does not motivate the litigant (but mixed motives?).

- An ***objective test***: litigation could be used for improper purposes when when there is a probable cause for the litigation in case it is suppressing competition. Economic test:
  - "if the expected value of a judgment is $10,000 (say, a 10% chance of recovering $100,000) the case is not "groundless"; yet if it costs $30,000 to litigate, no rational plaintiff will do so unless he anticipates some other source of benefit. If the other benefit is the costs litigation will impose on a rival, allowing an elevation of the market price, it may be treated as a sham" (Posner)
  - No immunity when the value of a favorable judgment, discounted by the uncertainty of prevailing, is less than the cost of suit
  - Does not take into account deterrence effects (difficult to calculate)?
  - Discourages the filing of a legitimate or novel claim
  - When baseless? At the time filed or when a party maintains a baseless lawsuit?

United States

- **Professional Real Estate Investors v. Columbia Pictures (1993): objective and subjective two part test**
  - The lawsuit must be
    - objectively baseless: no reasonable litigant could realistically expect success on the merits and
    - Subjectively improper, i.e. conceals an attempt to interfere directly with the business relationships of a competitor
  - Only if the challenged litigation is objectively meritless, may a court examine the litigant's subjective motivation
  - **Proving that litigation is a sham merely strips a litigant of antitrust immunity, it does not impose liability by itself**

- **Most recently,** *Federal Trade Commission (FTC) v. AbbVie*, Civ. No. 14-5151 (ED Penn. 2018)
  - AbbVie was accused to have filed baseless patent infringement lawsuits against potential generic competitors paired with a pay for delay strategy
  - The District Court determined that AbbVie had subjectively intended to directly interfere with its generic competitors' business. The Court applied a high standard of proof, i.e., by clear and convincing evidence "that defendants had actual knowledge that the patent infringement suits here were baseless".

Europe I

- ***Case T-111/96, ITT Promedia,* ECLI:EU:T:1998:183 *(1998)***
  - Bringing legal proceedings may constitute an abuse only in **exceptional circumstances**, namely where
  - (i) the action cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and would therefore serve only to "harass" the opposite party **and**
  - (ii) the action is conceived in the framework of a plan whose goal is to eliminate competition (intent test)
  - This would only be supported if the two limbs were interpreted and applied restrictively in a manner which does not frustrate the general rule of access to courts
  - Legal proceedings constitute an abuse "only if they cannot reasonably be considered to be an attempt to assert the rights of the undertaking concerned and **can therefore only serve to harass the opposing party**…"
  - The second criterion is satisfied solely "when the action did not have that aim, that being the sole case in which it may be assumed that such action could only serve to harass the opposing party"
  - The two conditions "must be construed and applied strictly"

Europe II

- **Case T-119/09 Protégé International Ltd v. Commission, ECLI:EU:T:2012:421 (2012)**
  - Is the intent of the plaintiff “to harass”? The conduct “can … only serve to harass”. Any alternative explanation trumps the finding of an abuse
    - –Direct documentary evidence
    - –Inference
      - »“The action must be objectively unreasonable or manifestly unfounded”: a demand that goes being the asserted rights
      - »“devoid of any basis in law”: e.g. the patentee conceals previous invalidation by a patent office during the suit
  - Part of a larger plan whose goal is to eliminate competition
    - –Pattern of exclusionary measures (e.g. started proceedings in other jurisdictions, an individual request for an injunction may not be on its own abusive)
    - –What about exploitation? (forcing the potential licensee to concede onerous licensing terms?

Europe III

- **Case T-480/15, *Agria Polska sp. z o.o. and Others v European Commission*, ECLI:EU:T:2017:339 (2017)**
  - The GC found that sham litigation had an ‘exceptional nature’ (para. 71)
  - It noted that, in the case of vexatious litigation, as well as that involving the abuse of regulatory procedures., ‘the administrative and judicial authorities seised by the undertakings in a dominant position concerned *had no discretion* as to whether it was appropriate to follow up or otherwise the applications made by those undertakings, whether that was a counterclaim brought before a national court or the decision of an undertaking to withdraw its application for authorisation to place a medicinal product on the market’ (para. 70, emphasis added). Indeed, ‘the court to which that counterclaim was made was *required* to rule on it’ (ibid.).
  - The case law of the EU courts has narrowed down the scope of the vexatious litigation category of abuse, denying its application in instances in which the public authorities whose process may serve as the means of the abuse can adopt their decision independently of the information supplied by the defendants (para. 71) and/or exercise some discretion
  - In the circumstances of the present case the authorities seised did have such a discretion, therefore no vexatious litigation was found
  - **Confirmed by Case C-373/17P, Agria Polska sp. z o.o. and Others v European Commission, ECLI:EU:C:2018:756, paras 56-58 (2018)**

Alternatives to antitrust to reduce sham litigation

- **Antitrust is not the only means to curve frivolous litigation:**
  - Model Rules of Professional Conduct: an attorney is not to file an action unless there is a basis in law and fact for doing so that is not frivolous"
  - Rule 11 of the Federal CPR requires an attorney to attest that the action "is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation". It requires a minimum amount of due diligence prior to initiating an action. With regard to patents this requires "at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement. The rule does not however apply to the continuation of a frivolous action.
  - Section 285 Patent Act: a court may award reasonable attorney's fees in exceptional cases, involding bad faith, frivolous suits, vexatious litigation, or other types of misconduct effectuated in either litigation or in securing a patent.
  - However these are inadequate deterrents: remedies (no treble damages), high evidential burden.

Enforcement of a fraudulently obtained patent I

- ***Walker Process Equipment****:* a defendant in a patent suit may bring an antitrust counterclaim where the allegedly infringed patent was obtained by fraud on the PTO. He must show by clear and convincing evidence that
  - *–The patent holder was enforcing a fraudulently obtained patent: this includes a* ***misrepresentation of a material fact****, the* ***falsity of that representation****, the* ***intent to deceive****, a* ***justifiable reliance upon the representation*** *by the party deceived and* ***injury to the party deceived as result of misrepresentation***
  - *–In order to* ***perpetuate a scheme to monopolize***
- *Walker Process* fraud constitutes a cause of action separate from *PRE*

Enforcement of a fraudulently obtained patent II

- In Europe: ***AstraZeneca*** – fraudulent misrepresentations to procure IP rights which can take place in front of a Patent Office (during opposition and appeal procedures) or a national court (during patent litigation)
  - ***Where the discretion of the administrative authority is limited, the cause of the anticompetitive effect resulting from a decision based on inaccurate information is not State action, but the misrepresentations***
  - Commission attempted to distinguish from *Promedia* and the intent test
  - Broader than in the US where there should be evidence of a link between representation and harm
  - ***GC*** (Case T-321/05 (2010)]: the misleading nature of representations made to public authorities must be assessed on the basis of ***objective factors*** and that proof of the deliberate nature of the conduct and of the ***bad faith*** of the undertaking in a dominant position is ***not required*** for the purposes of identifying an abuse of a dominant position
  - The limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to raise ***regulatory obstacles to competition***
  - No enforcement of the IP right is necessary

Enforcement of a fraudulently obtained patent III

- **CJEU: Case C-457/10 P, AstraZeneca (December 2012)**
- The Court of Justice affirmed the reasoning and holdings of the General Court and rejected all of AstraZeneca's arguments, including its challenge to the General Court's analysis of the definition of the relevant markets and the findings that AstraZeneca's IP and regulatory strategies related to its product Losec constituted an abuse of a dominant position in violation of Article 102 TFEU
- First abuse: ***submission of misleading information to public authorities***
  - AstraZeneca's deliberate attempt to mislead the patent offices through "consistent and linear" conduct consisting of" highly misleading representations" and a "manifest lack of transparency," fell ***outside the scope of competition on the merits***. (para. 93)
  - Even if AstraZeneca considered its interpretation was reasonable and that it had a serious chance that its interpretation would be accepted, the *onus was on AstraZeneca to disclose all relevant information to the patent office* so the office could decide, with full knowledge of the facts, which authorization it wished to accept for the purpose of issuing the SPC. The Court held that AstraZeneca knowingly accepted that the patent offices granted it SPCs which they would not have issued had AstraZeneca been transparent. .
  - Dominant companies do not need to be "infallible" in their dealings with regulatory authorities and that ***each objectively wrong representation will not necessarily be an abuse*** (para. 99)
  - "the *assessmen*t of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made **in concreto** and may vary according to the specific circumstances of each case." (para. 99)
  - dominant companies would not be considered to have engaged in abusive conduct simply because a patent application was struck down when challenged: "[it] thus cannot be inferred...that any patent application made by such an undertaking which is rejected on the ground that it does not satisfy the patentability criteria automatically gives rise to liability under Article [102]." (para. 99)

Enforcement of a fraudulently obtained patent IV

- Second abuse: ***withdrawal of the marketing authorizations***
  - ***GC***: AstraZeneca's withdrawal of the marketing authorizations for the original version of Losec was abusive as it ***delayed access to the market of generic producers and restricted parallel trade*** in the original capsule version of Losec. The withdrawal of the marketing authorization did not involve the legitimate protection of an investment that came within the scope of competition on the merits because AstraZeneca's exclusive right to make use of the data on its tests and clinical trials had expired. AstraZeneca had failed to establish an objective justification for the withdrawal because it did not show that the continued maintenance of the marketing authorization would result in a significant burden.
  - The fact that AstraZeneca was entitled under the relevant pharmaceutical legislation to withdraw the marketing authorization was irrelevant to the assessment of whether the withdrawal constituted an abuse.
  - ***CJEU***: a dominant company is entitled to adopt a strategy to minimize erosion of sales and deal with competition from generics
  - The fact that AstraZeneca was entitled to request the withdrawal of its marketing authorizations "in no way causes that conduct to escape the prohibition laid down in Article [102 TFEU]." "[T]he illegality of abusive conduct under Article [102 TFEU] is unrelated to its compliance or non-compliance with other legal rules." (para. 132)
  - the possibility to deregister a marketing authorization is not equivalent to a property right meaning that the behavioral limitations placed on the dominant company by virtue of Article 102 TFEU do not constitute an "effective appropriation" of such a right or an obligation to grant a license (para 149)
  - Innovative companies should not refrain from acquiring a comprehensive portfolio of intellectual property rights, nor should they refrain from enforcing them (para. 188)

‘Evergreening’ or ‘line extension’ and product hopping

- a situation in which a brand-name pharmaceutical company switches from one version of a drug (eg capsule, injection) to another (eg tablet, syrup), or any other reformulation of the drug (changing molecule parts or combine two or more drug compositions that had previously been marketed separately), while encouraging doctors to prescribe the reformulated rather than the original product, with the main purpose to shift (‘migrate’) the market to the reformulated drug and thus impair the entry of generics
- These practices may go as far as slightly changing an active ingredient and presenting an old medicine as a new product and registering a new patent, thus extending well beyond the protection period of the patent covering the active ingredient of the previously marketed product. [European Commission, Pharmaceutical Sector Enquiry – Final Report (2009), available at ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf]
- UK Gaviscon Decision No. CA98/02/2011, Case CE/8931/08 (April 12, 2011), available at http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.oft.gov.uk/shared_oft/ca-and-cartels/rb-decision.pdf

Conclusion: the interaction between competition law and IP

- The inherency of scope of the patent doctrine
- Balancing approaches
- Complementarity and “exceptional circumstances”
  - Sham litigation
  - Regulatory abuses (fraud to the patent office)
  - SEPs and injunctions
- Article 101 and pay for delay settlements