# Competition law and IP in the pharma industry

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# Some facts on the pharma industry I

- The average cost of developing a new drug and bringing it to the market has been estimated at over 1.3 billion $, a tenfold increase since 1975 (shift from traditional chemical compounds to biotechnology)
- Originators spend on average 17% of their global turnover from prescription medicines on R&D
- 80% of marketed products fail to recoup the average capitalized R&D expenditure made on them
- It will not be until 10-12 years after initial discovery and patenting of a compound that that a product will be launched on the market
  - An innovator can recoup its developments costs in substantially less than the 20 years of patent duration – system of Supplementary Protection Certificated (SPC) provides additional period of exclusivity protection for medical innovations
  - Patent protection may expire while a particular therapy retains its market attractiveness
- Market characterized by intense state regulation
  - Prices – States cut down (Germany mandates that physicians should prescribe an available generic product)
  - Provision of reimbursement status

# Some facts on the pharma industry II

- Difficult to make a breakthrough: most diseases are well researched
- Low pace of innovation (e.g. UK Deloitte, 2015)
  - R&D returns have declined from 10.1 percent in 2010 to 4.2 percent in 2015
  - Smaller companies remain more effective in generating value than bigger companies
  - Firms increasingly favour returning money to shareholders (or share buybacks) over new R&D investments
- M&A frenzy in pharma
  - Separation of R&D: Pharma focuses on D, buys the R (small biotech start-ups)
  - Antitrust authorities have been too lenient, at least when it comes to drug company mergers (e.g. Haucap & Steibale, 2016)
    - Acquirers often target firms that have a relatively similar patent portfolio - less competition for discovering and developing new therapies
    - Companies defend themselves by buying actual and potential competition
  - Merged companies have on average, worse performances than the group of non-merging firms (e.g. Omaghi, 2009)
- Big pharma socialises the risk (public funding of fundamental research), but privatises rewards

# 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 e.g. “reverse payments”
  - –(ii) **unilateral practices** by dominant firms which by abusing the regulatory and litigation system, or more broadly “gaming” the 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
  - ‘***product hopping***’ (also called ‘evergreening’ or ‘line extension’)
  - 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)
  - **excessive prices**
  - **limiting generics’ competition**

# Competition concerns I

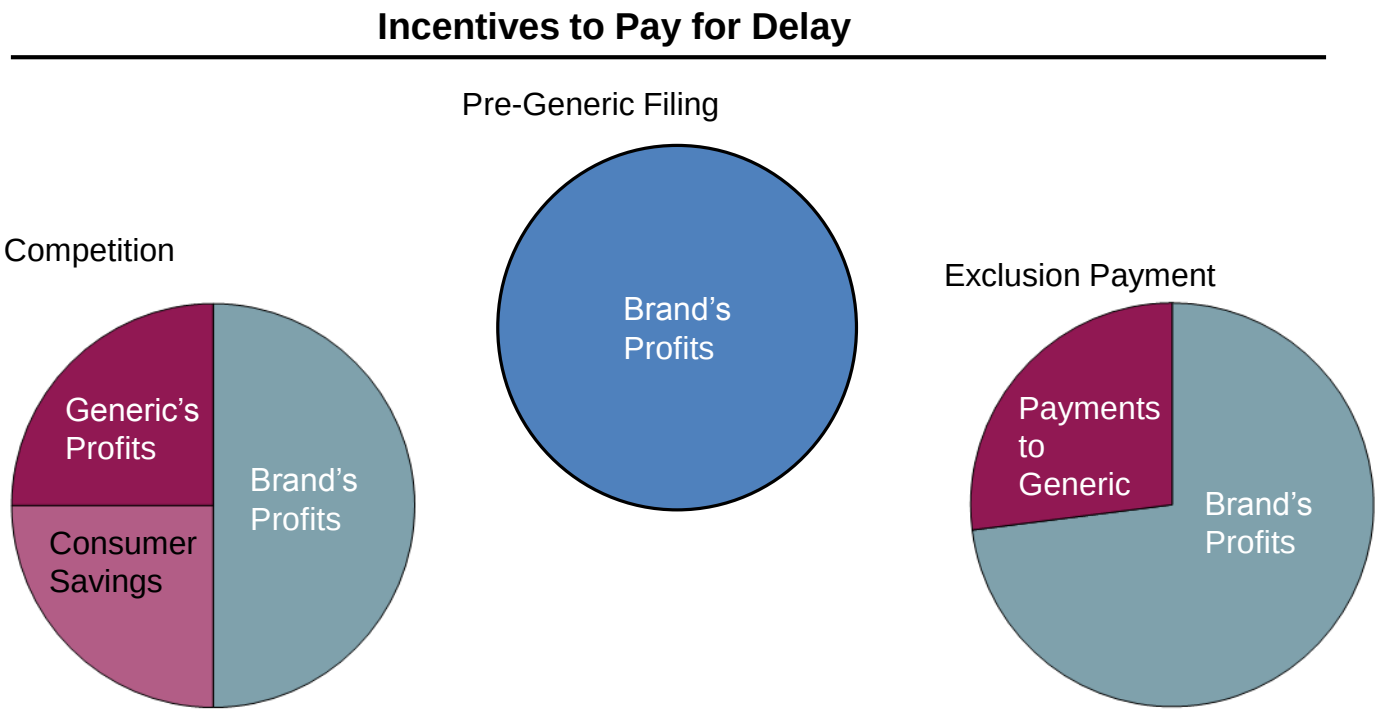
- Originators use a tool-box of patent-related practices that contribute to delays in generic entry
- Possibility of enforcing competition law
- Dominance?
  - Which relevant market?: Anatomical Therapeutic Chemical (ATC) Level 3: 5 levels, from level 1 (main groups) to level 5 (chemical substance): international standard for classifying medicines – broad
    - Other factors: patient usage, dosage levels, competition from off-label prescribing, threats from generic products
    - Astra/Zeneca (T-321/05, 2010): ATC4 class
  - Presence of monopsonist buyers (State, health services)

# Competition concerns II

- Settlements
  - Upward trend for patent litigation (60.000 patents per year in the EU)
  - Litigation expenses are high (discovery, cross-examination)
  - Typical terms in settlement agreements
    - Arrangements for withdrawing litigation
    - A commitment not to challenge the validity of the IP right again
    - Geographic or subject matter trademark delimitation agreement
    - Agreements as to the priority of an IP right
    - Granting a licence or having a future supply relationship
    - Sharing of costs (of litigation)

# Reverse Payments

"As illustrated below, by eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete":



# Competition concerns III

- Sham/vexatious litigation
- Regulatory abuses
- Excessive prices
- Limiting generics' competition

# SHAM/VEXATIOUS LITIGATION

# The rise of IP litigation

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

– European Commission, *Pharmaceutical Sector Inquiry* – Final Report (2009), *ibid*., pp 202–253 and 394–415

- 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 significant in view of the fact that patent infringers (in this case generics) face multiple actions in multiple states, given the absence of a unified EU patent system [however see, UPC (2017)]

- A considerable increase in recent years of litigation by Patent Assertion Entities (PAEs)

# A Public or a Private Restraint?

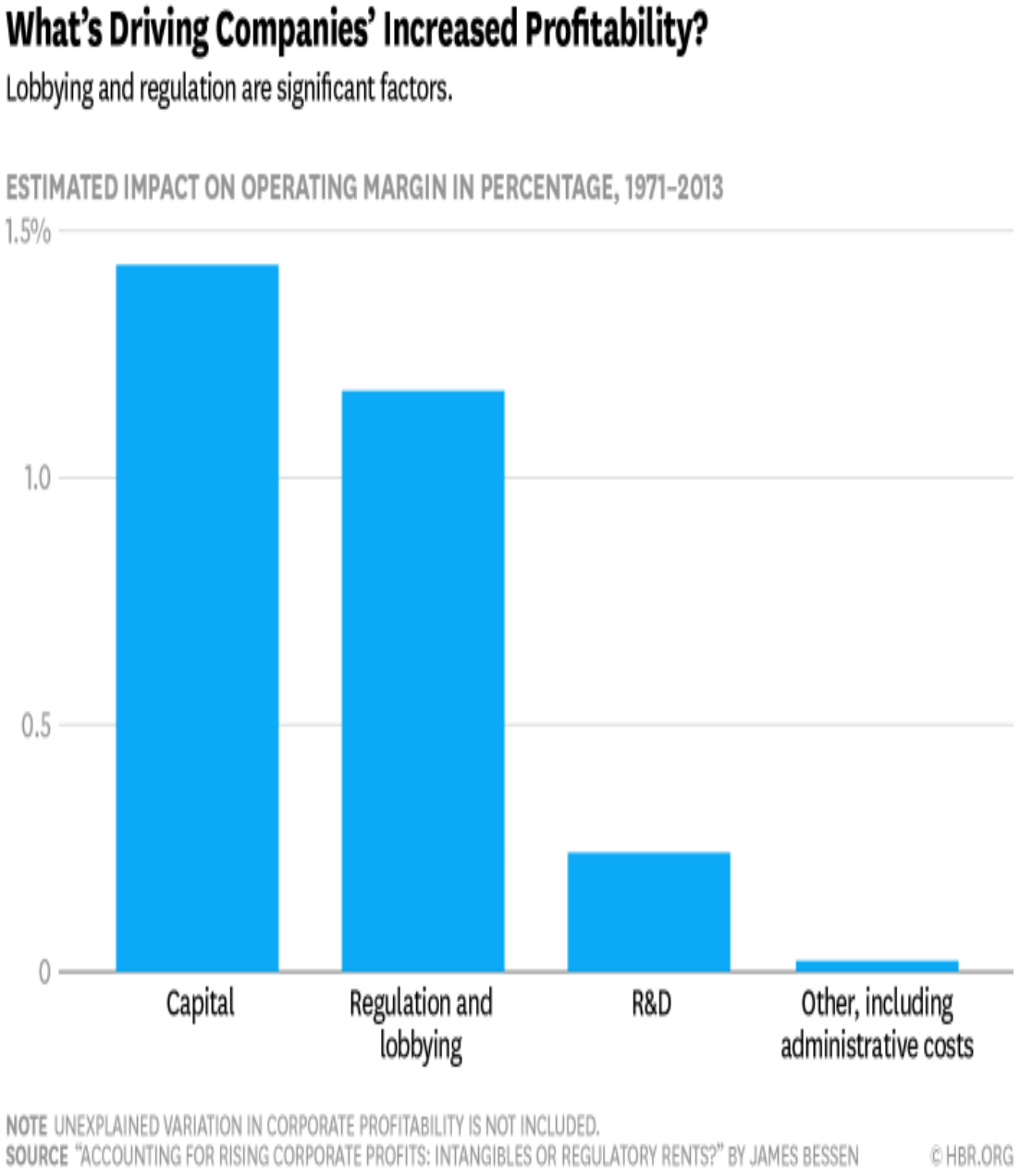
•A common characteristic of this type of cases is that it encompasses situations in which ***undertakings use the governmental process as an anticompetitive weapon***.

•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



# 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 courts

# 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.
  - An 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 is it baseless? At the time filed or when a party maintains a baseless lawsuit?

**Mainly cases in the US, EU and Brazil, but also in other jurisdictions (see WIPO Report, 2012)**

# Europe

***Case T-111/96, ITT Promedia (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

***Case T-119/09 Protégé International Ltd v. Commission (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 beyond 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?)

# 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**
- **Antitrust is not the only means to curve frivolous litigation. *Alternatives*:**
  - 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 US 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".
  - Section 285 Patent Act: a court may award reasonable attorney's fees in exceptional cases, involving 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.

**In the EU: Abuse of right "*a rebours*"?** Article 54 and Art. 17(2) Charter

# REGULATORY ABUSES

# 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 (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)

# EXCESSIVE PRICING

- European Commission has declined to open an investigation into allegations of excessive prices for Hepatitis C drugs in 2014, alleging that “pursuant to Article 168(7) TFEU, Member State may […] take measures to regulate or influence the prices in these areas. For this reason, price-setting by pharmaceutical manufacturers and healthcare systems in general takes place on a national level, allowing Member States to exercise their bargaining power”
- CMA, SO to Pfizer and Flynn (2016) - anti-epilepsy drug
  - prices which were between 25 and 27 times higher than those historically charged by Pfizer.
  - Pfizer also continued to manufacture the drug selling it to Flynn at prices that were 8 to 17 times higher than its historic prices
  - CMA considered the prices as “very high”

# REDUCING GENERICS' COMPETITION

- Competition authorities in Europe and the US have been quite proactive in preserving the effectiveness of generic competition once the original patent has expired, to protect generics from various strategies adopted by the patent holders. Different forms of exclusivity:
  - New Chemical Entity exclusivity (NCE)
  - Clinical Investigation Exclusivity
  - Orphan Exclusivity
  - Pediatric Exclusivity
- FCA: patent holder's 'denigration strategy' aimed at convincing healthcare professionals to limit prescriptions and sales of generic
  - *Sanofi-Aventis* (2013), confirmed by Court of appeal (2014), Supreme Court (2016)
  - *Schering-Plough* (2013)
- OFT (CMA)
  - *Gaviscon* (2011)
  - *Fine and subsequently NHS v. Reckitt Benckiser* (settled 2014)

# OPTIONS TO PROMOTE INNOVATION AND COMPETITION LAW/IP INTEROPERABILITY

# Possible options: A Substantive perspective

**Competition law may internalize IP values**: competition law should move towards a more dynamic analysis that focuses on innovation, instead of static allocative efficiency

- e.g. innovation markets, accept uncertain dynamic efficiencies in the welfare trade-off

**IP law may also internalise competition law values** by focusing on access **and** dissemination

- E.g. US FTC 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (October 2003)) available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>, Recommendations 6 and 10 has suggested the possibility for the Patent Office (PTO) to "consider possible harm to competition along with other possible benefits and costs, before extending the scope of patentable subject matter"

# Possible options: An institutional perspective

**More social science/economics learning in IP and competition law decision-making and adjudication**

- US PTO established in March 2010 the Office of the Chief Economist (OCE)
- The European Patent Office (EPO) established the position of a chief economist already in 2004
  - Economic and Scientific Advisory Board (ESAB) (2011)

Hargreaves (2011): **"broaden the IPO's vision"** and base IPO's decision-making in evidence and the obligation to "take due account of the impact of the IP system on innovation and growth"

**The development of "trans-disciplinary links" between competition authorities, IP law offices and courts**

- Joint policy statements: e.g. US DOJ & USPTO, 'Policy Statement on Remedies for Standard-Essential Patents Subject to Voluntary F/RAND Commitments' (8 January 2013)
- Systematic cooperation: e.g. Memorandum of Understanding between the Intellectual Property Office and the Office of Fair Trading (July 2012)

# Other mechanisms for incentivizing innovation

**Technology transfer** and international R&D agreements (through trade, FDI by MNE, technology licensing, cross-border movement of technical and managerial personnel)

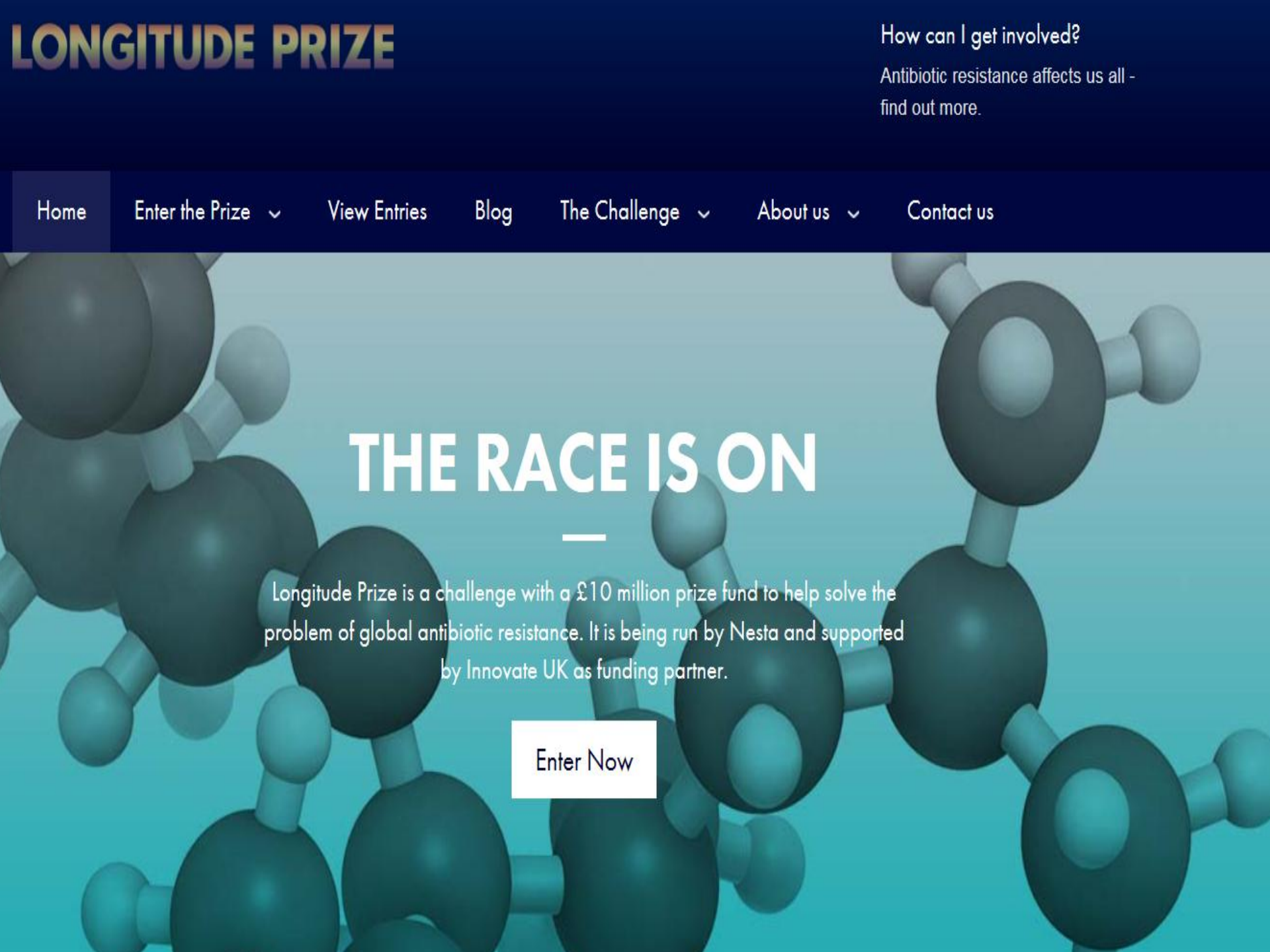
**Public research system** (public universities and laboratories, Institutes of health)

**Public funding of business performed research**

- Public procurement: government purchases research from private parties
- Subsidies (allocated on a competitive basis or by simple administrative decision
- Prizes: payment funded out of general revenue that is made to a researcher conditional on delivering a specified invention/International prizes (e.g. Longitude prize)
- Soft loans: reduced interest rate, guarantee of reimbursement by the State in case of success
- Tax incentives: reduced taxation on profits in proportion of research expenditure
- Public/Private Partnerships (e.g. MMV)


- Attempts to overcome patent system's failure to address issues of social value (versus willingness to pay) and distributive justice by using government and philanthropic funding and reputational rewards
- Relies on market's advantages in industry expertise
- Retains exclusive licenses to IPR resulting from its projects for malaria drug development, generally royalty-free

- Not-for-profit foundation – 63% funded by Gates Foundation, $800M funding
- Manages a portfolio of malaria drug projects from discovery through distribution
- Does not do in-house R&D – everything is done through "partnerships" – essentially grants
- Most notable successes have been with new formulations (e.g. pediatric) of known medications
- But a few new drugs are in clinical trials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THE RACE IS ON
Longitude Prize is a challenge with a £10 million prize fund to help solve the problem of global antibiotic resistance. It is being run by Nesta and supported by Innovate UK as funding partner.
Enter Now

Thank you for your attention

For more detailed analysis on the interaction between competition law and IP see

I. Lianos, Competition Law and Intellectual Property (IP) Rights in Competition Law Analysis, Cases and Materials (Hart Pub. 2017 Forthcoming). Available at SSRN: https://ssrn.com/abstract=2863814