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Access to Health Technologies, Patents and Prices: Capacity-building Consultation on the Use of Competition Law to Promote Affordable Access

Session 3: Evidence and Remedies in Competition Law Investigations

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UNDP

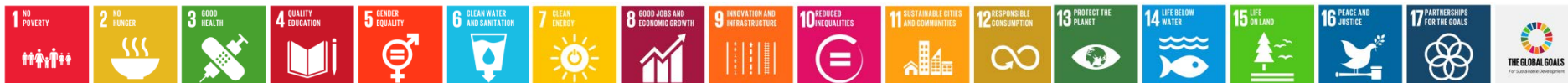
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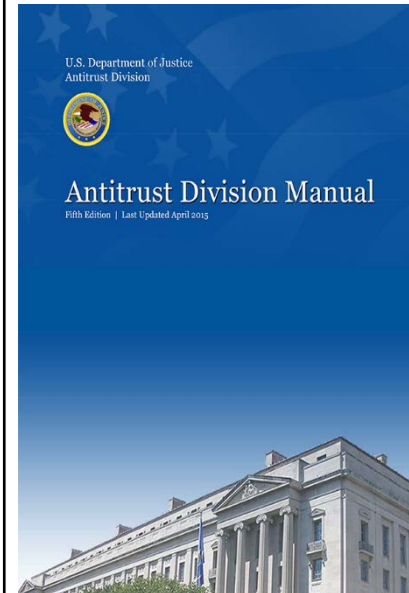
Sources of Information Initiating CA Investigations



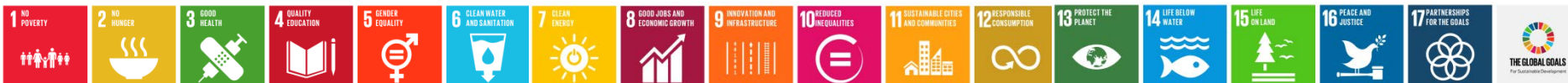
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Information sources (adapted from US Dep't of Justice Manual)

- Complaints received from citizens and businesses when they believe that companies or individuals are engaged in unlawful conduct.
- Analysis and evaluation of filings under premerger notification rules.
- Press reports of various practices that come to the competition authority's (CA) attention through the monitoring of a variety of media, including the Internet, newspapers, journals, and the trade press.
- Information obtained from informants or individuals or companies applying for leniency.
- Complaints and information received from other Government departments or agencies.
- Analysis of particular industry conditions by CA attorneys and economists, including systematic industry screenings.
- Monitoring of private antitrust litigation to determine whether the CA should investigate the matter.



<https://www.justice.gov/atr/file/761166/download>



Conducting Preliminary Investigation

- Civil and/or criminal?
 - Relevant factors, including statutory authority, type of violation, jurisprudence
 - In US, criminal prosecution generally reserved for "hard-core" violations
- Voluntary requests
 - Notification (due process)
 - Interviews (informal)
 - Documents

Compulsory Production



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- Compulsory production in civil cases, e.g., civil investigative demands
 - US DOJ - served on any natural or juridical person, including suspected violators, potentially injured persons, witnesses, and record custodians, if there is “reason to believe” that the person may have documentary material or information “relevant to a civil antitrust investigation.” 15 U.S.C. § 1312(a)
 - compulsory process “tool of choice” in civil antitrust investigations of potential violations of the Sherman Act



Types of Information – US Illustration



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- CIDs can require a recipient to produce specified documentary material, give sworn answers to written interrogatories, give a sworn oral deposition, or furnish any combination of such responses
- Should be mindful of the theory of the violation being investigated and should request the information needed to develop and establish the violation in accordance with that theory
- Every CID must identify the conduct being investigated and the statute potentially being violated
- It is a criminal offense intentionally to withhold, misrepresent, conceal, destroy, alter, or falsify any documentary material, answers to written interrogatories, or oral testimony that is the subject of a CID





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Investigative Process – US illustration

- CIDs for documentary material must describe the class or classes of documentary material to be produced thereunder with such definiteness and certainty as to permit such material to be fairly identified
- A CID for oral testimony must state the date, time, and place where the testimony will be taken and identify an antitrust investigator who will conduct the examination
- A CID deponent (i.e. person interrogated) may be accompanied, represented, and advised by counsel at the deposition
- US law permits deponent to invoke privilege against self-incrimination for criminal matters, but may be compelled to testify with immunity
- CID material may be used in connection with any court case or grand jury (i.e., criminal indictment), Federal administrative proceeding, or regulatory proceeding in which the CA is involved
- Grand juries used in criminal cases may issue subpoenas requiring production of evidence similar to CID. Individual targets may invoke privilege against self-incrimination



Search and Seizure



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- Circumstances in which CA may obtain authority to search premises without consent (e.g. search warrant) and seize evidence vary among national jurisdictions
- In United States, search warrants are available upon showing to judge that there is probable cause a crime has been (or is being) committed
- Sherman Act violations may be criminal and provide the basis for issuance of warrants to search and seize
 - “The use of search warrants, as opposed to subpoenas *duces tecum*, minimizes the opportunity for document destruction and concealment, prevents the failure to produce responsive documents either deliberately or through inadvertence, and often spurs a race for leniency.”
- In the U.S., the warrant must describe with particularity the property to be seized; state that the property is evidence of a specified criminal offense; provide an exact description of the location to be searched; note the period of time within which the search is to be executed



Immunity



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- In criminal antitrust cases, offers of immunity may be used to secure evidence from individuals who would otherwise invoke privilege against self-incrimination, or otherwise refuse to provide information
- Similarly, offers of corporate and individual leniency can encourage provision of evidence
- Individual "whistleblowers" may demand immunity if participant in the illegal activity, and may require protection against retaliation by employer
- Statutes may provide for whistleblower protection



Prosecution



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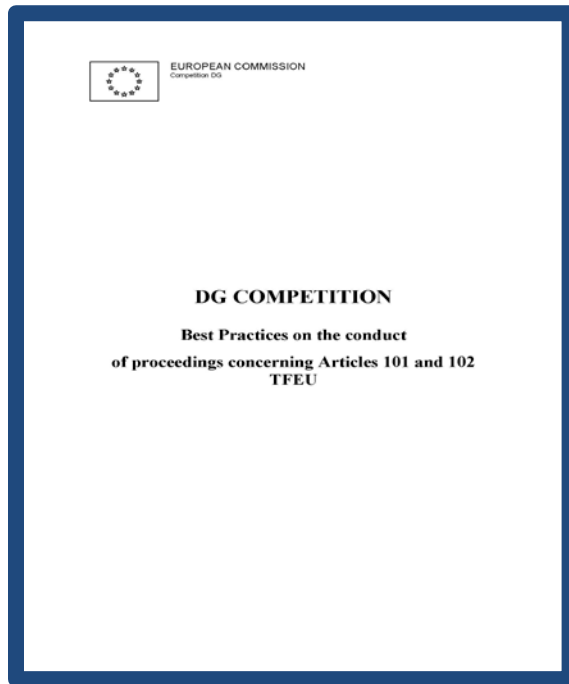
- Mechanism for initiation of court proceeding differs among jurisdictions
- Typically staff of CA will make recommendation to senior person or body laying out evidence, persons, potential defenses, etc.
- In US, it is typically for “Grand Jury” to indict (i.e. bring charges) for criminal violation
- Staff recommendations may include settlement or plea agreement



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- Commission notice on best practices for the conduct of proceedings concerning Articles 101 and 102 TFEU (Text with EEA relevance)
- http://ec.europa.eu/competition/consultations/2010_best_practices/best_practice_articles.pdf



Searches (Inspections) in EU



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ECN WORKING GROUP COOPERATION
ISSUES AND DUE PROCESS

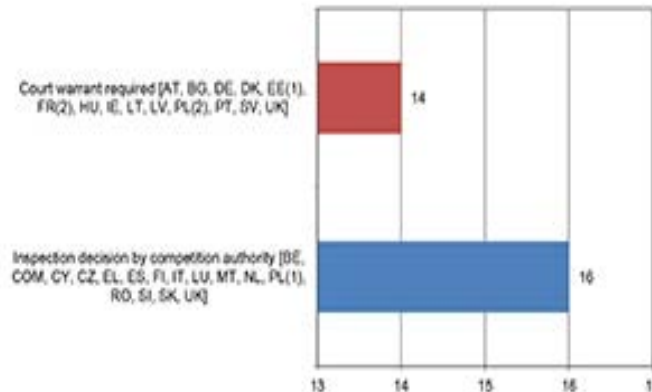
INVESTIGATIVE POWERS REPORT

31 October 2012

DISCLAIMER: This publication is a compilation of information received from national competition authorities of the European Union and the Competition Directorate General of the European Commission ("the Authorities"). Information provided in this publication is not exhaustive and is for information purposes only. It does not constitute professional or legal advice and does not give rise to legitimate expectations on the part of any undertaking or third party. The content of this publication is not binding and does not reflect any official or binding interpretation of procedural rules or the practice of any Authority. It does not represent the official position of any Authority. Neither any Authority nor any person acting on its behalf is responsible for the use which might be made of information contained in this compilation.

http://ec.europa.eu/competition/ecn/investigative_powers_report_en.pdf

Procedural requirements



Inspection
in business
premises

In DE [Germany], in exigent circumstances (i.e. a court order cannot be obtained in due time without diminishing the chances for success) the inspection may be carried out without a court warrant ... If the NCA seizes evidence and the undertaking objects to this, it has to apply for the required court order immediately (usually up to three days) after the inspection.



Inspections and Requests for Information Generally



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In the EU system, the COM, when encountering opposition, can rely on the assistance of MS authorities

In the UK, the competition authority has the power to enter premises to carry out inspections, either with or without a warrant. However, the power to carry out inspections without a warrant is limited to business premises and is subject to the UK competition authority having given the occupier of the premises at least two working days' written notice of the intended entry. For inspections with a warrant, the competition authority may apply to the High Court for a warrant under s.28 of the Competition Act 1998 ... In certain circumstances, the competition authority does not have to give advance notice of entry when acting without court warrant, for example if it has reasonable suspicion that the premises are, or have been, occupied by a party to an agreement which it is investigating, or if the authorized officer has been unable to give notice to the occupier, despite taking all reasonably practicable steps to give notice.

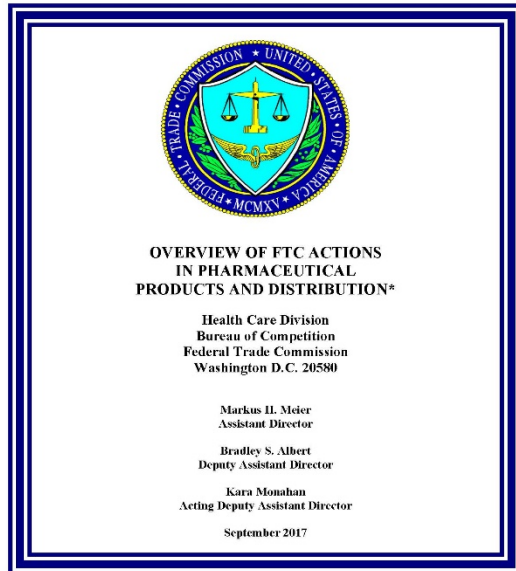
- All competition authorities have the power to request information in the context of investigations of competition law infringements.
- In most jurisdictions no distinction is made between a simple RFI and a compulsory RFI
- In the EU system, the COM can request information on the basis of Article 18(1) of Regulation 1/2003 as a simple RFI or on the basis of Article 18(3) in the form of a compulsory decision. Undertakings are obliged to answer to requests by decision but can refuse to reply to requests by simple letter.
- In principle, RFIs are binding on the addressee and refusal to answer may be sanctioned by the imposition of fines or periodic penalty payments
- In all jurisdictions, fines or penalty payments may be imposed in case of non-compliance or refusal by an undertaking to submit a reply to a RFI.
- In most jurisdictions, the competition authorities have the same powers for RFIs in the context of sector inquiries



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- FTC Competition in the Healthcare Market
- <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>
- https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_september_2017.pdf

* Actions involving health care services and products are contained in a separate document, *Overview of FTC Actions in Health Care Services and Products*. Information about advisory opinions in the health care and pharmaceutical sectors is contained in the document *Topic and Yearly Indices of Health Care Antitrust Advisory Opinions by Commission and by Staff*.



Remedies

- Remedial actions may be initiated by public authorities or private parties
 - In many jurisdictions, public authorities play principal enforcement role
 - Competition actions may be time-consuming and costly, involving significant evidence gathering
- USA may be unique in allowing private antitrust actions with triple damages
 - An encouragement to initiate and pursue claims

Settlement

- Common outcome of proceedings initiated by government authorities: target of investigation agrees to cease alleged anticompetitive conduct
 - May or may not include admission of wrongful conduct
 - May include target's payment of costs and/or civil penalty
- Settlement may be approved and issued as court order, sometimes referred to as "consent decree"
 - Advantage that courts may issue orders in event of noncompliance by targets without re-initiation of proceedings
 - May also include penalties and additional undertakings

Injunctions and Compulsory Licensing

- Successful public and private enforcement proceedings typically conclude with "injunction" directing accused to cease anticompetitive conduct and refrain from further such acts
 - May require restoration of *ex ante* conditions
- Injunction may direct target to undertake certain acts, including issuance of compulsory license, and may include pricing limitations (see, e.g., Canadian Price Review Board)
- TRIPS Agreement, Article 31, expressly recognizes authority to grant compulsory licenses to remedy anticompetitive practices, and waives certain conditions that otherwise may be applicable to compulsory licensing (prior negotiation with the patent owner, remuneration (as appropriate) and export restrictions)

Damages



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- Damages typically awarded in favor of injured party, which may be government acting on behalf of public
- The injured party must demonstrate to court or judge actual damages suffered using some reasonable basis
 - USA provides for triple damages without additional showing of bad intent
- Damages may include forfeiture of property acquired through anticompetitive means
- Although many countries object to USA authorization of triple damages, provides encouragement to private party claimants that may be important to generating action



Blocking Orders and Divestiture

- In many jurisdictions, mergers and acquisitions above a threshold size require notification to competition authorities (i.e. “pre-merger notification”) and are subject to review and approval by those authorities
 - Denials of approval may typically be appealed to the courts
- Assessments may include:
 - level of concentration of firms in the relevant industry
 - implications for competition in particular markets (and submarkets)
 - For originator and generic pharmaceutical companies, may consider the resulting situation as regards specific therapeutic classes and whether there is a risk that the combined firm will exercise undue control over a specific therapeutic class
 - whether the combined firms would create a risk of reduced competition in R&D in the development of new health technologies.

Blocking Orders and Divestiture

- In a number of jurisdictions competition authorities issue guidelines that should allow proposed combining firms to determine whether a combination is likely to be approved
- In terms of pre-merger review, competition authorities may establish as a condition of approval that combining firms divest themselves of certain properties or product lines
 - might require that a particular medicine line be transferred to third party whose products will compete with comparable products of the combining firm
- If competition authorities ultimately consider proposed combination anticompetitive may issue blocking order

Criminal penalties

- Anti-competitive conduct subject to criminal penalty (in addition to civil prosecution) in many jurisdictions
- Culpable individuals may be subject to imprisonment, and individuals and business entities subject to criminal fines
 - Under US Sherman Act, prohibited acts constitute felonies
 - Corporations may be fined \$100 million for a violation of each section; individuals may be fined \$1 million and may be imprisoned for up to 10 years.
 - Maximum fine may be increased to twice the amount conspirators gained from the illegal acts or twice the money lost by the victims of the crime, if either of those amounts is over \$100 million

Trends and Ideas for Remedial Actions for Pharmaceutical Sector

- Australia adopted legislation (Amendments to Therapeutic Goods Act, 2005) requiring pharmaceutical patent owners initiating legal actions under its patent/regulatory approval 'linkage' mechanism to certify they are proceeding in good faith against the generic company applying for market entry
- If court or administrative authority later determines patent claim not brought in good faith, patent owner subject to substantial fine and recovery by government of cost to public health system of delayed market entry
- Remedial orders more generally might include provisions designed to accelerate generic market entry, such as requiring originator to authorize generic producer to rely on drug approval master file