

Questionnaire A for National Reporters of LIDC Geneva 2016

"In the case of pharmaceuticals, in what way should the application of the competition rules be affected by the specific characteristics of those products and markets (including consumer protection rules, the need to promote innovation, the need to protect public budgets, and other public interest considerations)?" ?

Background

The International League of Competition Law is gathering information relating to pharmaceutical antitrust questions ahead of its October 2016 Congress in Geneva. The Congress will analyse the following question with a view to making recommendations:

In the case of pharmaceuticals, in what way should the application of the competition rules be affected by the specific characteristics of those products and markets (including consumer protection rules, the need to promote innovation, the need to protect public budgets, and other public interest considerations)?

The interaction of the pharmaceutical sector and competition law is potentially very wide-ranging, encompassing issues such as (i) anticompetitive agreements, such as market sharing and "pay for delay" restrictions on entry; (ii) monopolisation allegations, including price discrimination, excessive pricing, "evergreening" and product hopping; (iii) merger clearances; and (iv) competition law issues in licensing agreements. The special protection of drug originators under intellectual property law has the potential to pose unusually pronounced competition law issues.

With a view to determining whether Recommendations on shared practices can be made, the questions focus on: (i) whether pharmaceutical products receive differentiated legal treatment under competition law; (ii) whether any differentiated enforcement mechanisms exist, with particular reference to consumer protection; (iii) the interaction of pharmaceutical intellectual property protection and competition law; and (iv) whether there is shared practice on budgetary and other public interest considerations.

Your answers to these questions will form the basis of the Report for the Congress, and will be very greatly appreciated. Please do not hesitate to direct any queries to the International Rapporteur, Stephen Dnes, via e-mail at s.m.dnes@dundee.ac.uk.

1. The competition law context of the pharmaceutical industry

This section seeks to determine whether the treatment of pharmaceutical products is differentiated under the competition law of your jurisdiction.

- a. Which legislative provisions of your jurisdiction are most likely to be applied to a potential competition law infringement in the pharmaceutical sector? Please provide the text of the key provisions of this legislation.

- b. Is market definition in the pharmaceutical sector any different, compared with market definition in other industries, as a matter of law or as a matter of practice in your jurisdiction? Please give a brief account of the main decisions of competition authorities or court judgments on market definition in this sector, or of any specific legislative provision dealing with this issue.
- c. Is there a "per se" or "object" infringement rule by which evidence assessment tends to be truncated in pharmaceutical cases in your jurisdiction? If there are cases or decisions of competition authorities showing this rule in operation, please provide brief summaries of them.
- d. Is there difference in the scope to argue justification of restrictions of competition in pharmaceutical competition law cases in your jurisdiction, such as specific legislation or guidance? Is there any limitation tending to limit the scope to argue justifications for potentially restrictive conduct, such as a "per se" or "hardcore" rule?
- e. Is there any special legislation defining excessive or discriminatory pharmaceutical pricing in your jurisdiction, differentiating it from "ordinary" excessive or discriminatory pricing cases?
- f. Please comment on any other aspects that you consider to be relevant in which the legal treatment of pharmaceutical sector cases tends to be differentiated in your jurisdiction, compared with other competition law cases.

2. Enforcement mechanisms, remedies and consumer protection

This section seeks to assess whether there are special patterns of enforcement, such as the use of consumer protection law, specialist bodies, specialised remedies, and whether the balance between public and private enforcement differs in the case of the pharmaceutical industry.

- a. Is there any pattern by which pharmaceutical competition law issues in your jurisdiction tend to be dealt with primarily by laws against restrictive agreements, laws against monopoly, or by merger review?
- b. Does competition law interact with consumer protection law in your jurisdiction? If so, please provide examples of the interaction of consumer protection law and competition law.
- c. Are there any specialist bodies with responsibilities relating to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical regulator with a competition law competence, or a consumer protection body with specialist pharmaceutical competence? If so, please provide a brief description of the body and its powers.

- d. Please provide details of any sector-specific reviews of competition law in the pharmaceutical sector. Have any such reviews led to increased enforcement activities?
- e. Is there any set of guidelines particularly relevant to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical-specific set of guidelines or a set of competition law guidelines addressing intellectual property issues?
- f. Is enforcement in pharmaceutical cases primarily public or private in character? Does this differ from the situation in other industries?
- g. Which remedies tend to be applied in pharmaceutical competition law cases in your jurisdiction, such as fines, disgorgement of profits, damages, or injunctions?
- h. Is there a mechanism for the monitoring of patent settlements in the pharmaceutical sector, such as a register of patent settlements?
- i. Are pharmaceutical suppliers obliged in your jurisdiction to make available pharmaceutical products that they are licensed to sell? What is the extent of any such obligations?
- j. Are there any decisions of competition authorities or court judgments that deal with the application of the competition rules to agreements or conduct in relation to the distribution of pharmaceutical products (e.g. agreements between manufacturers and distributors or retailers or conduct such as refusal to supply)? To what extent do those decisions or judgments suggest that the application of the competition rules to the distribution of pharmaceutical products is affected by the characteristics of pharmaceuticals?
- k. Please comment on any other aspects that you consider to be relevant of the interplay of consumer protection law and competition law in the context of the pharmaceutical sector in your jurisdiction.

3. Innovation questions

This section gathers information relating to special treatment of pharmaceutical products to promote innovation, notably the treatment of originator patent protection by competition law in your jurisdiction.

- a. Is there legislation promoting generic entry in your jurisdiction? If so, please provide details of instances in which competition law analysis has been applied in the context of the legislation.
- b. A major aim of the report is to identify whether there is consistency across jurisdictions in the factors taken into account to assess the interplay of competition law and intellectual property law claims. Please comment on whether the following

factors tend to be taken into account when a court or regulator decides whether intellectual property has been exercised in an anti-competitive way in pharmaceutical markets.

- i. Do courts and regulators in your jurisdiction provide a shield for potentially anti-competitive conduct on the basis that it falls within the scope of intellectual property (sometimes referred to as a “scope of the patent” approach)?
 - ii. If so, how expansive is the protection? Does the mere presence of intellectual property trigger an absolute bar to competition law enforcement (e.g. allowing even a large reverse payment provided it is made within the patent term), or is a balance struck between the intellectual property right and competition law?
 - iii. Must an agreement exclude rivals to trigger competition law enforcement, or does it suffice for an agreement (e.g. pay for delay) to exclude only the party to the agreement?
 - iv. Are there examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in your jurisdiction?
 - v. Is the date of the settlement in the context of the patent term a relevant consideration?
- c. Please comment on any other relevant factors other than those already raised in question 3(b), if any, that tend to be looked at in pharmaceutical cases in your jurisdiction to adjudicate conflicts between competition law and intellectual property law claims.
- d. Please briefly comment on the barriers to entry typically faced by a generic drug maker looking to enter the market. Are there examples of these barriers being in any way artificially raised?

4. Public finance considerations

This section seeks to assess whether there is differential treatment of pharmaceutical competition law cases on the basis that public funds are involved, such as parallel trading bans to support price control.

- a. Some jurisdictions exempt certain bodies in the healthcare industry from competition law, such as by granting insurers or bodies exercising a public competence blanket exemptions or by not including them as relevant “undertakings”. Is competition law applied consistently to healthcare purchasers and providers in your jurisdiction? If it is not, what is the basis for differential treatment?
- b. Does enforcement on behalf of third party payers such as insurers or public funding bodies tend primarily to be public or private in character? Please comment on any relevant differences, if any, in the enforcement pattern on the basis that such bodies are involved.

- c. Please provide brief details of pricing controls of pharmaceuticals in your country. Do these differ if a public healthcare provider is purchasing drugs?
- d. If so, are there restrictions on parallel trade or resales of those drugs subject to price control? Are any such restrictions specific to pharmaceutical products, e.g. a special legislative provision, or do they merely reflect the application of ordinary competition law doctrine?
- e. Please comment on any other points of current differentiation that you consider to be relevant in the competition law treatment of pharmaceutical products in your jurisdiction that are made on the basis that public funds are involved.
- f. Please comment on any other public interest considerations you believe ought to be relevant to competition law analysis in the pharmaceutical sector, if any.

5. Any other considerations

- a. Please comment on any other aspects of the interaction of competition law and the pharmaceutical sector in your jurisdiction that you consider likely to be relevant to the League's Report and Recommendations.
