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.

Introduction to the Swedish report

This section will introduce certain aspects of Swedish law that may explain factors that are relevant in the answers (and which may differ from other legal systems). It cannot be emphasized enough the importance attached to the travaux preparatoires in the Swedish legal system. They are often used as a complement to the legal text as such and are therefore crucial for the interpretation of the legal statute. Accordingly, some references below are made to the travaux preparatories to different laws. The most

common travaux preparatoires used and referred to in this report are the proposal for new legal act (*proposition*, abbreviated as prop. followed by the year and number [prop. XX/XX:YY]) and the governmental reports preceding a proposal (*statens offentliga utredningar*, abbreviated as SOU followed by year and number [SOU XXXX:YY]).

Moreover, it should also be pointed out that there are few cases on competition law in general in the Swedish system. The competition law regime was changed in 1993 in order to adapt to the EU competition law regime with the introduction of Konkurrenslagen (1993:20) (KL 1993). Since then less than 30 cases of public enforcement (excluding merger cases) with fines have been tried by courts. Of these, none concern medical drugs. Most cases concerning pharmaceuticals are about the distribution of drugs and have primarily been handled at the level of competition authority. Most of the cases also stem from the initial period after the introduction of the competition law regime in 1993 due to the use of notification requirement (as was also used in EU competition law at that time). Thus, it could be questioned if the assessments made in these cases are still good law.

Finally, the law was changed in 2004 with the abolition of the notification system (following the modernization reform at EU level) and replaced in 2008 (with a few changes on sanctions) with Konkurrenslagen (2008:579) (KL). The changes in 2008 did not concern the formulation or the material content of the basic prohibitions against anticompetitive collusion or abuse of dominance. As regards anticompetitive mergers, the only change made in 2008 was a shift in the material assessment from a dominance test to a significant impediment of effective competition test. The purpose was to align the KL with EU competition law.

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.

Reply: Issues of competition law infringements are addressed by the general rules on competition law as stated in the Competition Act, Konkurrenslagen (2008:579) (KL). The KL is enforced by the Swedish Competition Agency, Konkurrensverket (KKV). Other rules that are relevant concern in particular the authorization of medical drugs, the regulation of trade in medical drugs as well as the subsidization of medical drugs from the public purse. Medical drugs are authorized by the Medical products Agency, Läkemedelsverket (LMV), according to the Medical Product Act, Läkemedelslagen (2015:315) (LL). In addition, trade with medical products is regulated by the Act on Trade with medical products, Lag (2009:366) om handel med läkemedel (LHL). Finally, the rules on

subsidization of medical drugs are stated in the Act on Pharmaceutical benefits, Lag (2002:160) om läkemedelsförmåner (LF). The Dental and Pharmaceutical Benefits Agency, Tandvård- och Läkemedelsförmånsverket (TLV), also takes decisions on prices for drugs that are subsidized (see below question 4 c).

As regards the general competition law rules, they encompass, as in European competition law, a prohibition of restrictive agreements (Ch 2, sections 1 and 2 KL), a prohibition of abuse of a dominant position (Ch 2 section 7 KL) and merger control (Ch 4 section 1 KL). There are no sector specific (competition) rules for the pharma industry and no rules that *de facto* encompass some form of application of the competition rules in the pharmaceutical sector.

Chapter 2 sections 1-2 KL, Chapter 2 section 7, KL and Chapter 4, section 1 KL, as translated by the KKV, state:

Anti-competitive cooperation between undertakings

Article 1
Agreements between undertakings shall be prohibited if they have as their object or e ect, the prevention, restriction or distortion of competition in the market to an appreciable extent, if not otherwise regulated in this act.

This shall apply, in particular, to agreements which:
1. directly or indirectly x purchase or selling prices or any other trading conditions;
2. limit or control production, markets, technical development, or investment;
3. share markets or sources of supply;
4. apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; or
5. make the conclusion of contracts subject to acceptance by the other par- ties of supplementary obligations, which by their nature or according to commercial usage have no connection with the subject of such contracts.

Exemptions from the prohibition on anti-competitive cooperation between undertakings

Article 2
The prohibition in Article 1 does not apply to agreements which
1. contribute to improving the production or distribution or to promoting technical or economic progress;
2. allow consumers a fair share of the resulting benefits;
3. only impose on the undertakings concerned restrictions which are indispensable to the attainment of the objective referred to in paragraph 1, and
4. do not a afford such undertakings the possibility of eliminating competition in respect of a substantial part of the utilities in question.

Abuse of a dominant position
Article 7
Any abuse by one or more undertakings of a dominant position on the market shall be prohibited.

Such abuse may, in particular, consist in
1. directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions,
2. limiting production, markets or technical development to the prejudice of consumers,
3. applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage, or
4. making the conclusion of contracts subject to acceptance by the other parties of supplementary

obligations, which by their nature or according to commercial usage have no connection with the subject of such contracts.

Ch 4 section 1

Prohibition against concentrations

Article 1
A concentration shall be prohibited, if it significantly restrains occurrence or the development of effective competition within the country as a whole, or a substantial part thereof. During the examination of the concentration and the question whether it will be forbidden account shall specially be taken to whether it creates or strengthens a dominant position.

A prohibition may only be carried out if no significant national security or supply interest will be set aside.

To the extent that the creation of a joint venture, which constitutes a concentration in accordance with Chapter 1, Article 9, second paragraph, has the aim or effect of coordinating the competitive behaviour of the undertakings which remain independent, in the examination of a prohibition against the concentration, the co-ordination shall be appraised in accordance with Chapter 2, Articles 1 and 2.

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.

Reply: There are few cases, concerning mostly mergers, that deal with market definition in the pharma sector. As those cases concern (favorable) decisions made by the KKV, the analysis of the relevant market is not exhaustive and somewhat superficial.

On a general level the approach to market definition in the pharmaceutical sector does not differ from the general competition law approach as applied to other industries. What may be seen as a particularity in the pharmaceutical industry is the emphasis put on the ATC-classification and active substance. The KKV acknowledged the use of the ATC-classification in Recept Pharma (dnr 1434/94) by the European Commission in particular the use the 3 level, ATC3, concerning the pharmacological/therapeutic subgroup. However, the KKV focused on the level 4 in the ATC-classification, the chemical subgroup, as the case concerned restrictions of parallel trade and thus the degree of substitutability was seen as more narrow. In case Merck (dnr 814/94) it was stated that relevant markets for medical drugs consist of the active substance and available substitutes, including generic drugs when patents for the original drugs have lapsed. This statement departed from the approach taken previously in the case Astra (dnr 1101/93) where a much broader approach was taken (antibiotics in general as opposed to antibiotics specifically including a particular active substance). The KKV never addressed the relation between the cases. The focus on active substance has also been followed in other cases such as DuPont (dnr 1163/95). In 2008 the

KKV made a distinction between prescribed drugs and non-prescribed drugs (Astra dnr 706/2008). In that case the KKV's held that end consumers when making choices between non-prescribed drugs tend to be more influenced by trademark than the active substance.

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.

Reply: While the object/effect distinction applied in EU Competition law also applies in Swedish competition law, there are no specific cases regarding the object and effect distinction applied in the pharmaceutical sector. The Stockholm City Court, Stockholms Tingsrätt (Sthlm TR), which is the court of first instance in some competition cases, stated recently (Case T 10057-14) that restrictions by object encompass forms of coercion that by their nature have negative effects on competition. This statement followed the ruling by Court of Justice of the European Union (CJEU) in Cartes Bancaire (Case C-67/13 P). As regards some of the older case law under the KL 1993 concerning either distribution of pharmaceuticals or licensing agreements referred to below in this report, the KKV did not always specify clearly whether the specific restriction constituted an object or effect restriction in individual cases.

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?

Reply: There are no such rules or practice.

e. Is there any special legislation defining excessive or discriminatory pharmaceutical pricing in your jurisdiction, differentiating it from "ordinary" excessive or discriminatory pricing cases?

Reply: No. As explained below, there is a price control mechanism applied to drugs that are part of the pharmaceutical benefits scheme in Swedish law (see above under introduction and below under question 4 c). Although the price regulation formula applied is not perfect and has been subject to discussion, there is probably little room for applying excessive prices. The very purpose of the price regulation system is to minimize costs for the public while providing a fair remuneration for manufacturers of pharmaceuticals. To market a pharmaceutical product effectively towards Swedish consumers it is probably necessary to make it part of the pharmaceutical benefits scheme. Thus, most pharmaceutical products are covered by the price controls in place.

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.

Reply: There are no such mechanisms.

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?

Reply: To begin with there are few cases in general regarding Swedish competition law. As stated above, the KKV has litigated less than 30 cases regarding fines at the court of first instance, Stockholms Tingsrätt, the Stockholm City court. Within the group of successful cases, none has concerned the pharma industry.

The cases on the pharma sector stem from the previous enforcement under the KL 1993 system that was based on a notification procedure that applied between 1993-2004 or early cases concerning mergers and acquisitions (see dnr 800/95). In that period, a certain emphasis was put on the distribution of pharmaceutical products as the retail market (pharmacies) was subject to a monopoly (subsequently tested under the EU rules on free movement in the case C-438/02 Hanner, ECLI: EU:C:2005:332).

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.

Reply: There is no such interaction. Enforcement of both kind of regulations are separated. The Swedish Competition Agency, Konkurrensverket (KKV), enforces rules of the KL as well as rules on public procurement, while the Swedish Consumer Ombudsman, Konsumentombudsmannen (KO), will handle cases on unfair marketing and certain types of unfair competition (also within the pharma-sector). In addition, there are rules on marketing (restrictions) that apply in the pharma sector. Compliance with these rules is a prerequisite to get a license to trade in pharmaceuticals (see e.g. Ch. 12 LL). The supervision and enforcement of those rules are handled by LMV.

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.

Reply: The LMV that supervises those companies that are granted license for manufacturing and trade in pharmaceuticals deal with certain aspects of marketing in order to protect consumers (Ch. 12 and 14 LL). The LMV does however not deal with competition law issues. The LMV has the right to impose sanctions such as prohibitions and injunctions as well as penalty payments (Ch. 14 LL). The TLV act as price regulator for drugs that are part of the pharmaceutical benefits scheme which has beneficial effects for consumers (see below question 4c). However, even of the body takes price decision, it does not really have a competition law competence. Moreover, the TLV does not have pharmaceutical competence (such decisions, like e.g. which drugs that are regarded as substitutable, are left to the LMV).

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?

Reply: The KKV made an inquiry to the distribution of medical drugs following the liberalization of the retail monopoly for the sales of medical drugs (see decision dnr 340/2007). The liberalization of the sector was due to, inter alia, the judgment made by the Court of Justice in C-438/02 Hanner (ECLI: EU:C:2005:332) where it was found that the retail monopoly (pharmacies) was susceptible to discrimination of foreign drugs and thus contrary to Article 37 TFEU (then Article 31 TEC). Additionally, it was believed that liberalization would increase supply and enhance consumer service (e.g. better opening hours). The KKV:s sector inquiry purported in particular to identify behavior by the ex-monopolist that could potentially harm the liberalization process. Amongst the measures suggested by the report was the separation between the former monopolist (that would continue to act within the market retailer of drugs) and certain infrastructure that at the time was deemed crucial for new entrants into the retail market for medical drugs. Although the inquiry also identified exclusive agreements between manufacturers and wholesale distributors as potentially problematic, it did not result in enforcements actions. It was expected that the liberalization would give room for more actors in the market, which could break up the existing competition restrictions in the market.

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?

Reply: There are no such guidelines. However, it is my assessment that Swedish competition law is expected to follow the interpretations made in EU Competition law as regards the assessments made of intellectual property rights (IPRs). Block exemptions in Swedish law, including those on R&D agreements (lag (2008:583)) and technology transfer agreements

(lag (2008:586)) make a cross-reference to the block exemptions made by the Commission in EU Competition Law. Thus, apart from minor details, the substantive Swedish rules follow the norms adopted in EU law. Accordingly, the KKV is also expected to follow the interpretation made by the Commission in soft law instruments as regards competition law issues, including the treatment of intellectual property rights. Thus, it is likely that the KKV will follow the Commission's guidelines on horizontal cooperation agreements (OJ 2011 C 11/1) and technology transfer agreements (OJ 2014 C 89/3) as regards the the treatment of IPRs.

f. Is enforcement in pharmaceutical cases primarily public or private in character? Does this differ from the situation in other industries?

Reply: There have not been cases regarding the pharmaceutical industry after the reform of the enforcement system in 2004 (like regulation 1/2003 at the EU level), excluding merger cases. There is therefore no data whether cases in the pharmaceutical sector are primarily handled through private or public enforcement.

Cases under the KL 1993 emerged through the notification system and thus through public enforcement. The pharmaceutical sector was not treated differently than 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?

Reply: As there are practically no pharma cases it is not possible to make a proper assessment of this issue. The current rules in antitrust mainly give room for fines (Ch. 3 section 5 KL). Although there is also, theoretically, the possibility to impose a trading prohibition (Ch. 3 section 24 KL), this will only apply to hardcore cartel cases and does not seem to be relevant for competition problems specific to the pharmaceutical sector. In the merger control area there is of course the possibility to require divestment (Ch. 4 section 2 KL) or to accept divestments as part of commitments offered by the parties (Ch. 4 section 4 KL).

h. Is there a mechanism for the monitoring of patent settlements in the pharmaceutical sector, such as a register of patent settlements?

Reply: There is no obligation to register patent settlements. Licensing agreements (which in theory may be the result of patent settlements) may be registered by the PRV *upon request* by the parties according to the Patent Act, Patentlagen (1967:837) (PL), Ch. 4 section 44.

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?

Reply: A distinction is made between holders of a marketing authorization for a medical drug

and wholesale traders.

As regards holders of marketing authorization, there is no general obligation to supply. In a recent proposal to change rules in the LL such an obligation has been rejected *inter alia* because it was found that such an obligation could deter manufacturers of drugs to enter the Swedish market (prop. 2013/14:93, p. 99). However, for those products that are included in the pharmaceutical benefits scheme and that are selected as the product of the period by the TLV section 21(a) LF imposes an obligation to supply. This obligation was introduced in 2015 as a countermeasure to combat the existing problems of failure to supply (by pharmacies) individual end-consumers (prop. 2013/14:93, pp. 165-168). This is intended to give an incentive for the supplier of the product make available sufficient drugs within the particular period (of one month). If the supplier cannot make the products available for the relevant period, its medical drug cannot be selected as the product of the period. If a supplier fails to supply the selected product of the period, it may be subject to an administrative fine under Section 25 of the Act on dental and medical benefits (2002:160) imposed by the TLV.

As concerns wholesale traders, it follows from Ch. 3 section 3 LHL that the requirements to get a license from the LMV is that the trader will supply the medical products covered by the license to pharmacies. In case the requirements are not met the LMV may ultimately withdraw the license.

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?

Reply: There are decisions from the competition authority on the distribution of pharmaceuticals under the KL 1993. Importantly, during that period there was a monopoly for the sales of pharmaceuticals at the retail level (Apoteket), which was later abolished in 2009.

The particular features of those decisions are the permissive approach by the KKV to accept exclusive distribution agreements between manufacturers and wholesale distributors. In principle, a "one channel distribution system" was in place meaning that one product should only be distributed through one distribution channel. Moreover, at the distribution level there were only two competitors. One of these competitors (ADA, later Tamro) was also owned by Apoteket. This apparent and admitted restriction of competition was justified with the necessity to secure the supplies of the drugs and make such supplies cost-efficient (see e.g. the KKV´s decisions dnr 185/1998 Kronans Droghandel, dnr 971/93 Kronans Droghandel, dnr 1220/93 ADA). The elimination of competition at the distributor level was e.g. found to

eliminate costs for marketing towards retailers and decreasing costs for storage of sufficient stocks of drugs. The approach seems to have been accepted in the light of the (artificial) market structure as well as an overall goal to keep costs low for pharmaceuticals. Occasionally, there were complaints about refusal to supply from other actors than retailers when trying to obtain pharmaceuticals directly from the manufacturers (see e.g. KKV decision dnr 184/1998). In the KKV report (KKV decision dnr 2007/340) it is stated that the liberalization of the retail market in pharmaceuticals could change the assessment of existing exclusive distribution agreements (see above question 2(d)). In a KKV case (dnr 993/2000), after intervention from the KKV, the monopolist at the retail level, Apoteket, withdrew its plans to take over all distributions to its retailers which would have eliminated the competition at the distribution level. Additionally, the KKV has also found the refusal to supply by a dominant distributor (ADA) to a company engaged in parallel export as an abuse of a dominant position (dnr 1434/94).

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. 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.

Reply: Although it may be discussed whether the main focus of LHL is consumer protection, it has some consumer protection/competition law aspects. The act anticipated possible problems with vertical integration with negative effects on consumers The rules prevent e.g. doctors and drug manufacturers from running pharmacies. (2 kap 5 § LHL, see also the prop. 2008:09145, pp. 144-146.

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.

Reply: In Sweden the State subsidizes the use of medical drugs for the purpose to aid patients. According to Chapter 4 Section 22 LL, the LMV decides which products that are medical equivalents and thus substitutes for a particular drug. In order for a patient to benefit from state granted subsidies (by paying a lower price), pharmacies are required to expedite

the cheapest available substitute (Section 21 LF). The TLV decides which is the cheapest product within a group of medical drugs for a particular period (the product of the period) and that should be chosen by pharmacies. A patient may of course refuse to take a generic version of a drug or any other substitute but has then to cover the difference in price from his/her own pocket. The doctor prescribing the drug may however on beforehand object to any substitution. This system of substituting drugs at the pharmacy level was introduced to promote and increase price competition between on the one hand original drugs and the other hand generic drugs or parallel traded drugs (see prop. 2001/02:63, p. 58). While the proposal to the Act (2002:160) does not include any particular competition law reasoning, it seems as that the main purpose was to increase price competition to give incentives drug manufacturers to lower prices which, in turn would result in lower costs for the subsidizing of medical drugs from the public purse.

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)?

Reply: No. The Swedish rules are expected to be interpreted in the light and in conformity with the EU competition law (which follows from the proposal to the KL 1993, prop. 1992/93:56 pp. 21 and 62). At the same time there has not been any cases of the same dignity as the cases in the IPR-Competition law intersection in EU competition law. One example is the KKV´s decision in the Nobel Biocare case (dnr 645/96) under the KL 1993 concerning a licensing agreement. The KKV acknowledged that IPRs are restrictive of competition (because of their exclusivity) but also that they give incentives for competitive behavior. The KKV also stated that the IPR holder could legitimately protects its interest defined by the IPR as well as the interest of the licensee. A similar statement can also be found in the KKV´s decision in Marabou (dnr 1338/93). The approach taken by the KKV in these cases under KL 1993 indicates that the scope of the patent doctrine was not applied in a formalistic manner and that it was acknowledged that restraints (going beyond the patent scope) may also be legitimate to protect the licensee. There are no later cases that would express a different stance in Swedish competition law towards IPRs. Moreover, as stated above, it is expected that Swedish law is likely to follow the position taken by the European Commission, which does not follow the patent scope doctrine.

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?

Reply: No. As explained in the previous question, there is a balance of interest made. The presence of an IPR does not result in absolute bar for competitor law enforcement and the underlying (innovation) interests are taken into account.

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?

Reply: There are no pay for delay cases. There is nothing in the law or practice that would suggest that only the exclusion of a rival would be captured by the law.

iv. Are there examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in your jurisdiction?

Reply: Not relevant. There are no such cases triggering the application of competition law.

v. Is the date of the settlement in the context of the patent term a relevant consideration?

Reply: Not relevant.

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.

Reply: Not relevant.

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?

Reply: The most important instrument to increase competition from generic drug maker has been the substitution system according to section 21 LF. As late as in a governmental report from 2012 (SOU 2012:75, Ch. 14, pp. 619-676), the system was deemed as effective and successful in pushing down prices and thus health cost for the state. Inevitably, substitution does not occur because of customer inertia, or because generic drugs do not work for the patient. However, all in all, it seems as the substitution system had decreased entry barriers for generic drug makers to a large extent.

A problem that has emerged recently is the conclusion of agreements between manufacturers of medical drugs and the counties (landstingen) that procure medical drugs. In one case such an agreement included the obligation for the county to not recommend the substitution of the medical drug according to section 21 LF. Thus the county would encourage those in charge of prescribing

drugs to oppose substitution. In exchange the county would receive a rebate on purchased drugs. As a result, this could make it harder for generic drugs that are cheaper substitutes to benefit from the facilitated entry into the market created by the pharmaceutical benefits scheme (see question 3a). The TLV took measures against the agreement in question (on basis of the LF interpreted in the light of EU Transparency Directive, 89/105/EEC) but lost the case at the Supreme Administrative Court, Högsta Förvaltningsdomstolen, (the so-called Cimzia case, no. 3596-14). The court seems to have acknowledged that the existence of such agreements could be contrary to the requirements on transparency imposed through EU law, but it also found that there was no legal basis for the sanctions taken by the TLV. This case arguably exposes a lacuna in the LF which could permit circumvention of the rules on substitution of drugs.

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?

Reply: The term undertaking is interpreted in line with EU competition law. In an early case under the KL1993 the KKV found that a regional authority executing obligatory public health services by *purchasing/procuring* health services did not constitute an undertaking under competition law (dnr 1434/93 VSSO). The KKV was ambiguous as whether the public health services executed by the Regional authority constituted economic activity. Arguably, the offering of public health services which are not qualified as economic activity could mean that the purchasing activity of by such an entity would not be captured by the KL. Such a view would also correspond to the current position on the matter in EU Competition Law. In any case, whether the non-economic activity exclusion is applicable must be assessed from case to case and should not be interpreted as a blanket exemption.

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.

Reply: Not relevant.

c. Please provide brief details of pricing controls of pharmaceuticals in your country. Do these

differ if a public healthcare provider is purchasing drugs?

Reply: The main price control occurs through the subsidy scheme for medical drugs, the so-called pharmaceutical benefits scheme, that are sold by retailers (pharmacies) to consumers, the so-called outpatient pharmacies. The TLV determines the price for drugs that are accepted to the pharmaceutical benefits scheme according to Sections 15-17 LF. The TLV determines the price of purchase by the pharmacies as well as the sales price to consumers. The pharmaceutical benefits scheme is constructed in such a way that a consumer will pay a maximum amount for medical supplies during a year (the high-cost protection scheme). The rest is subsided by the state. The TLV takes decisions on whether a product is included in the pharmaceutical benefits scheme after an application by private parties (primarily the company marketing the product, section 8 LF). As regards sales that occur to other parties (like a hospital) than outpatient pharmacies there are no price controls, even when the drug in question is part of the pharmaceutical benefits scheme.

The two main factors in the price decisions taken by the TLV are the cost-effectiveness and marginal benefit. Cost-effectiveness means in this context that the cost of the drugs must be reasonable from a medical, humanitarian and socio-economic point of view. The term marginal benefit refers to the availability of other more suitable drugs. These two factors are interdependent, as the higher the marginal benefit of a drug, the higher price can be found to be reasonable (see TLV Guidelines referred to below).

(For more information on the assessment made by the TLV and the different relevant factors in the setting of prices see http://www.tlv.se/Upload/English/ENG-guide-for-companies.pdf).

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?

Reply: The requirement for wholesale traders to supply pharmacies (see above question 2(i)) covered by their license may in practice restrict parallel trade as this may be a difficult requirement to meet for parallel imported medical drugs. In fact, the reason why the supply obligation has not been extended to include all medical drugs sold by pharmacies is that such a requirement would constitute an entry barrier at the wholesale level (prop. 2008/09:145, pp. 157-160).

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.

Reply: Not relevant.

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.

Reply: No additional comments.

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.

Reply: No additional comments.
