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U.S. DEVELOPMENTS

U.S. Supreme Court denies certiorari in reverse payment case

On 22 June 2009 the U.S. Supreme Court <u>denied</u> certiorari in a reverse payment settlement case (Arkansas Carpenters, et al. v. Bayer AG and Bayer Corp., et al., Docket 08-1194). Earlier, the Federal Circuit held in the case that such a settlement was not anti-competitive because it fell within the exclusive scope of the patent rights (In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 f.3d 1323 (Fed. Cir. 2008), see <u>Newsletter 1/2008</u>, p. 2).

The approach of near per se legality of reverse payment settlements that do not extend beyond the scope of the patent, applied by the Federal Circuit and the 2nd Circuit, has been heavily criticized and, as noted below, has also been addressed in a recent amicus brief by the Department of Justice in the 2nd Circuit. Nonetheless, despite these concerns and the potentially conflicting approaches adopted in other circuits, the U.S. Supreme Court denied the petition for certiorari. [Juha Vesala]

U.S. DOJ files amicus brief on reverse payment settlements

On 6 July 2009 the U.S. Department of Justice filed an <u>amicus brief</u> in a reverse payment settlement case on appeal before the 2nd Circuit (In re Ciprofloxacin Hydrochloride Antitrust Litigation). The filing is in response of an invitation by the Court to address, in particular, the question whether reverse payments violate antitrust laws. The Court has previously considered such settlements virtually per se legal if they do not extend beyond the scope of the patent (In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006)).

The brief, first, explains the dynamics of patent infringement suit settlements involving reverse payments in the context of the Hatch-Waxman Act. It, in particular, notes the risk of potential generic competition that a settlement can remove by eliminating the possibility that the patent in question is not infringed or is invalidated.

The brief, second, addresses the appropriate antitrust standards for reverse payment settlements. Because agreements to settle patent infringement suits may serve efficiency enhancing purposes, the brief does not consider per se illegality appropriate but that such settlements should be evaluated under the rule of reason.

Presumptive anti-competitiveness. However, the brief argues settlements involving substantial reverse payments should be presumptively anti-competitive, because payments to a generic firm can be viewed as consideration for the generic firm delaying its entry. Without the payment, a settlement agreement either would have allowed earlier entry or, absent the settlement agreement, the patent could have been held invalid in litigation. A prima facie case would according to the brief be made by showing that

- 1) a generic manufacturer withdrew its validity challenge,
- 2) money or other consideration flowed from the patent holder to the generic firm, and
- 3) the payment accompanied the agreement to withdraw the validity challenge.

No consideration of the whether the patent holder likely would have prevailed in the patent suit is necessary or even appropriate according to the brief.

Rebuttal of the presumption. The brief would, however, allow defendants to rebut the presumption that the reverse payment purchased reduced competition beyond the situation that reflects the parties' contemporaneous views. If the defendants show that the reverse payment did not exceed the litigation costs avoided by the patent holder, the presumption would be clearly rebutted as such amounts do not suggest a departure from the expected outcome in litigation. Payments not greatly in excess of avoided litigation costs would be unlikely to significantly harm competition.

In case of payments greatly in excess of avoided litigation costs, the rule of reason analysis would focus on the terms of the settlement, in particular, the nature and extent of generic competition allowed. In case *no generic competition* is allowed *before patent expiration*, the defendants would not be able to justify the agreement. This is because the settlement eliminates the possibility of generic competition before patent expiry.

Settlements that do provide for *generic entry before the expiration of the patent* can be justified by defendants if the agreement preserved a degree a competition reasonably consistent with the parties' expectations on the outcome of litigation. It is the defendants' burden to show the terms of generic entry reflected their contemporaneous evaluations on whether a judgment would have resulted in generic competition before patent expiration. The defendants can justify the agreement by providing a reasonable explanation that the reverse payment purchased something else than exclusion from the market, in which case there is no reason for finding that the settlement diverges from the competition consistent with the parties' contemporaneous expectations. [Juha Vesala]

U.S. Supreme Court grants certiorari in NFL licensing case

On 29 June 2009 the U.S. Supreme Court granted certiorari in a case involving the licensing of NFL team logos and trademarks for team products such as headwear (American Needle, Inc. v. National Football League, et al., Docket 08-661). The teams had granted the exclusive right to license their logos and trademarks to an entity that subsequently granted an exclusive license to a headwear manufacturer.

At issue before the Supreme Court is, first, whether the NFL and its member teams acted as a single entity in such licensing of the NFL team logos and trademarks. If no collective action among separate entities is present, no violation of Section 1 of the Sherman Act can occur. Earlier in the case, a district court found that in the exploitation of their intellectual property rights the teams acted as a single entity rather than in cooperation, and thus granted motion to dismiss. The 7th Circuit affirmed, stating that it was unnecessary to consider whether the member teams could have competing interests in the exploitation of their intellectual property rights and thus could compete in the licensing and marketing of their intellectual property.

At issue before the Supreme Court is, second, whether the exclusive arrangements among the NFL teams and with the headwear manufacturer are subject to rule of reason analysis in view of the obligations not to compete in the licensing or sales of the team products. [Juha Vesala]

9th Circuit remands antitrust claims against VeriSign

On 5 June 2009 the 9th Circuit <u>reversed (in part) and remanded</u> antitrust claims concerning the operation of the .com and .net domain name registries in a case brought against VeriSign (Coalition for ICANN Transparency, Inc. v. VeriSign, Inc, 567 F.3d 1084 (9th Cir. 2009)). VeriSign operates these registries pursuant to contracts with the Internet Corporation for Assigned Names and Numbers (ICANN).

Whereas the district court granted VeriSign's motion to dismiss the claims, the 9th Circuit held that the plaintiff adequately stated .com related conspiracy and monopolization claims. In particular, the plaintiff adequately alleged that VeriSign and ICANN conspired to eliminate competition in the bidding for future contracts to administer the .com registry and that they further conspired to set artificially high prices for VeriSign's services. The plaintiff also adequately alleged that VeriSign monopolized or attempted to monopolize the .com registration market by coercing ICANN into these agreements through various improper means.

The Court also remanded similar .net related claims and claims about attempted monopolization of expiring domain names. [Juha Vesala]

EU DEVELOPMENTS

Commission publishes final report on competition enquiry in the pharmaceutical sector

On 8 July 2009, the European Commission published its <u>final report</u> on the <u>pharmaceutical sector inquiry</u>. The report's conclusion is that the market is not functioning as well as it could, mainly due to delays in entry of generic medicines to the market. It also notes the decline in novel medicines.

The sector inquiry has concentrated on company behavior, focusing on two issues:

- The competitive relationship between originator companies (companies that develop and sell new patented drugs) and generic pharmaceutical companies. In particular, it has considered whether there are obstacles to market entry for generic companies caused by the practices of originator companies.
- The competitive relationship between originator companies. It has considered whether there are there obstacles to market entry for originator companies caused by practices of competing originator companies.

In particular, the Commission considers that originator companies are using a number of methods to extend the commercial life of their medicines and to prevent or delay the entry of generics. However, the Commission recognizes that, while company practices are among the causes of the delay in generic entry, the problems are also caused by shortcomings in the regulatory framework.

The report highlights several different specific delaying strategies, including the following aimed at generic companies:

 Patenting strategies, such as patent clusters: Some originator companies have over time changed their patent strategies in recent years in order to develop strategies to extend the breadth and duration of their patent protection. In particular, the use patent clusters (filing numerous patent applications for the same

- medicine) has become more frequent, often with the clear aim to delay or block market entry of generic medicines.
- Disputes and litigation against potential generic competitors:
 Although patent enforcement is legitimate and a fundamental right, however, the Commission has found that litigation can also be an efficient means of creating obstacles for generic companies, whereas in certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.
- Patent settlements with generic companies: Originator companies also concluded more than 200 settlement agreements with generic companies in the EU, in which they agreed on the terms for ending an ongoing litigation or dispute. About half of settlements restricted generic entry and in a number of cases there was a direct payment (reverse payment settlement) from the originator to the generic company.
- Various interventions and launch of follow-on products: Originator companies also intervened in national procedures for the approval of generic medicines in a significant number of cases, which led to delays of some months in generic market entry. In addition, the Commission also found that in many instances, originator companies launched second generation/follow-on drugs, generally some months prior to loss of exclusivity, often to delay the market entry of generic products corresponding to the first generation product.

Moreover, the regulatory framework can cause delays through its lengthy marketing authorization and its pricing and reimbursement procedures, whereas the lack of a single Community patent and as well as of a unified and specialised patent litigation system further result in higher costs and inefficiencies in the system.

As a result, the Commission declared that it will apply increased scrutiny under EC Treaty antitrust law to the sector and will pursue any antitrust infringement wherever required by the Community interest. For instance, in February 2008 launched an antitrust investigation into German drugs group Boehringer amid allegations the firm has acted to keep competitors out of the market for certain respiratory drugs. Boehringer's conduct seems to concern misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease drugs. There appear to be some parallels with the AstraZeneca case of two years ago, when the Commission ended up fining the firm €60 Million for misusing the patent system and the procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug.

At any rate, the Commission will use all of its powers, including the merger control (and state aid) rules, as the pharmaceutical sector is currently going through a significant phase of consolidation, whereas originator companies are acquiring generic companies and generic companies are merging with each other.

On the other hand the Commission will push for the establishment of a Community patent and of a unified specialised patent litigation system in Europe, as these measures would result in significant cost and efficiency improvements, whereas legal certainty would be enhanced by avoiding conflicting rulings. The Commission will also urge Member States to take further action, such as providing an automatic/immediate pricing and reimbursement status for generic medicines that are equal to the original products, as well as introducing legislation that facilitates generic uptake, such as prescription by substances rather than brands. [Gabriele Accardo]

European Commission considers commitments proposed by Rambus

On 12 June 2009 the European Commission <u>published commitments</u> proposed by Rambus which, if subsequently made binding by a Commission decision, allow the investigation of the licensing practices of Rambus to be closed.

The Commission is of the preliminary view that Rambus has abused its dominant position by demanding unreasonably royalties for its Dynamic Random Access Memory patents following deceptive conduct (patent ambush) within a standard-setting organization. According to the Commission, absent the intentional deceptive conduct, Rambus would not have been able to charge as high royalty rates as it does, rendering the conduct an infringement of Article 82 EC Treaty in this context.

While Rambus does not agree with the facts and the legal analysis, it has in order to meet the competition concerns identified by the Commission proposed commitments that include maximum royalty rates for chips and memory controllers and a most-favored-customer clause. They would be applicable over a five-year period following a commitment decision.

Commission investigates alleged anticompetitive practices hindering entry onto the market of a generic cardio-vascular medicine

On 8 July 2009, the European Commission <u>announced</u> the opening of a formal investigation into suspected breaches of Article 81 and Article 82 of the EC Treaty by Les Laboratoires Servier and a number of generic pharmaceutical companies.

The Commission is investigating Les Laboratoires Servier's alleged abuse of a dominant position and a number of agreements between that company and various generics companies. It is concerned that Les Laboratoires Servier's conduct and these agreements may have had the object or effect of hindering entry onto the market of a generic cardiovascular medicine originally developed by Les Laboratoires Servier.

The investigation in the present case is not, strictly speaking, related to the pharmaceutical sector inspections the Commission carried out in January 2008 nor to the pharmaceutical sector enquiry the result of which were published also on 8 July 2009. However, in seeking to improve the Commission's knowledge of a sector, sector inquiries are "upstream" of any antitrust proceedings in specific cases, which may or may not follow.

The investigation follows a number of unannounced inspections, also know as "dawn raids", carried out in November 2008 by the Commission with the co-operation of the national competition authorities of several EU Member States. [Gabriele Accardo]

EC's public consultation on the new Block Exemption Regulation and Guidelines on Vertical Restraints

On 28 July 2008, the European Commission <u>launched</u> a public consultation to review the Block Exemption Regulation ("BER") and the Guidelines on vertical restraints, which are set to expire in May 2010.

As the Commission puts it, two major developments have marked the tenyear period following the adoption of the current rules: an increase in large distributors' market power and the evolution of sales on the Internet. Accordingly, the draft revised rules on which stakeholders are consulted have been adapted to take account of these two developments. The majority of the changes are included in the revised <u>draft Guidelines</u>.

The dual market shares threshold. The Commission proposes that for a vertical agreement to benefit from the <u>block exemption</u>, not only the supplier's market share (as is the case under the current rules) but also the buyer's market share should not exceed 30%, a change which the Commission deems necessary to take account of the further increase in large distributors' market power.

Internet sales. The draft Guidelines include new provisions on Internet sales in relation to restrictions of passive/active sales within exclusive and selective distribution systems. Manufacturers of expensive goods, notably luxury/branded goods or electronics are lobbying fiercely the Commission to allow for tighter rules on Internet selling.

As a preliminary issue, the draft Guidelines address the distinction between active and passive sales. They reiterate the principle that every distributor must be free to use the Internet to advertise or to sell products and that, in general, the use of the Internet/the setting up of a website is not considered a form of active sales, since it is a reasonable way to reach every customer, unless it is specifically targeted at these customers. However, online advertisement specifically addressed to certain customers is now expressly considered a form of active selling to these customers, while, conversely, general advertising or promotion on the Internet that reaches customers in other distributors' (exclusive) territories or customer groups but which is a reasonable way to reach customers outside those territories or customer groups, for instance to reach customers in one's own territory, are considered passive sales.

In addition, the following are now explicitly considered as hardcore restrictions of passive internet selling:

- Requiring a (exclusive) distributor to prevent customers located in another (exclusive) territory from viewing its website or requiring the distributor to re-route automatically customers to the manufacturer's or other (exclusive) distributors' websites;
- Requiring a (exclusive) distributor to terminate transactions if the credit card data reveal an address that is not within the distributor's (exclusive) territory;
- Requiring a distributor to limit the proportion of overall sales made over the internet;
- Requiring a distributor to pay a higher price for products to be resold online than for products intended to be resold off-line.

Conversely, under the draft Guidelines a supplier may legitimately "restrict" Internet sales by requiring his distributors to have a brick and mortar shop or showroom before engaging in online distribution as well as requiring quality standards for the use of the Internet site to resell his goods, just as the supplier may require quality standards for a shop or for advertising and promotion in general. However, any obligation which dissuades appointed dealers (i.e. within a selective distribution system) from using the Internet by imposing criteria for online sales which are not equivalent (albeit they do not have to be necessarily identical to those imposed for off-line sales) to the criteria imposed for the off-line sales will be regarded by the Commission as a hardcore restriction (of passive selling).

Moreover, the restriction of passive sales during the first two years that a distributor is selling the contract goods or services fall outside Article 81(1) when such distributor is the first to sell a new brand or the first to sell an existing brand in a new (geographic) market. Allowing such an absolute

restriction of passive sales appears particularly relevant for branded (e.g. luxury) products which are the most affected by Internet sales, notably due to counterfeits and free-riding issues.

Other changes in brief. The revised Guidelines contain the majority of the "new" provisions. These are aimed chiefly to either clarify general issues, or to address issues not covered in the current Guidelines, among which the following:

- Resale Price Maintenance. RPM is still regarded as a hardcore restriction. Notwithstanding, the draft Guidelines underline the possibility for an undertaking to substantiate, in individual cases, the likely efficiencies that RPM restrictions may bring about. Fixed or minimum retail prices may be justified/necessary to align the interests of the distributors with the interest of the supplier (typically where a manufacturer introduces a new brand or enters a new market), or to organize coordinated short term low price campaigns which may benefit consumers; or also to limit the potential negative effects of loss-leading activities by distributors.
- Agency agreements. The draft Guidelines introduce a further category of risk (related to other activities, in other product markets) to determine whether an agent is a true agent or a distributor. The draft Guidelines suggest to assess whether the principal requires the agent to undertake such activities and these activities are indispensable to engage in selling or purchasing the contract goods or services on behalf of the principal.
- Upfront access payments and category management agreements. The draft Guidelines now address two types of agreements not discussed in the current Guidelines: upfront access payments (practices whereby suppliers pay fixed fees to distributors in order to have access to their distribution network) and category management agreements (where the distributor entrusts the supplier, i.e. the category captain, with the marketing of a category of products including in general not only the supplier's products, but also the products of its competitors).

The draft Guidelines make also clear that while the BER does not apply to unilateral conduct, as long as the unilateral policy of one party receives the (explicit and/or tacit) acquiescence of the other party, then such acquiescence constitute a vertical agreement for the purpose of the application of Article 81 EC. Moreover, while in general the Commission bears the burden of proof that an agreement falling outside the scope of the BER actually infringes Article 81(1), the new draft Guidelines now clarify that including hardcore restrictions in an agreement gives rise to the a rebuttable presumption that the agreement falls within Article 81(1), and that the Commission may simply rely on such a presumption to base a

finding that the agreement in question infringes Article 81(1). [Gabriele Accardo]

European Commission welcomes Microsoft proposals on web browsers

On 24 July 2009 the European Commission welcomed the proposal by Microsoft to include a ballot screen for consumers to select the web browser(s) they wish to use with Windows.

Under Microsoft's proposal, Windows 7 would include Internet Explorer but consumers could easily choose to install competing web browsers by means of the ballot screen. In addition, OEMs would be able to install competing web browsers and disable the Internet Explorer.

The Commission has not yet determined how the proposed solution will affect its case against Microsoft but will investigate whether the proposals would remedy the concerns raised by the tying of the Internet Explorer to Windows. [Juha Vesala]

European Commission opens in-depth investigation in Sun Microsystems / Oracle

On 3 September 2009 the European Commission <u>announced</u> it has opened an in-depth investigation under the EC Merger Regulation of the acquisition of Sun Microsystems by Oracle Corporation. Competition concerns prompting the in-depth investigation were identified in the market for databases, on which Oracle and Sun offer directly competing products in various sectors.

According to the Commission, Sun's MySQL, offered as an open source product, is widely seen as an increasingly important competitive constraint in the concentrated database market. Oracle, IBM and Microsoft control approximately 85 % of the market in terms of revenue.

The Commission is concerned that the open source nature of Sun's MySQL might not be sufficient for avoiding the competition concerns. Therefore the Commission will, in particular, focus on the incentives of Oracle to further develop MySQL as an open source database. [Juha Vesala]