Annex B (to KEI March 7, 2014 Special 301 comments)

KEI Research Note: Recent European Union Compulsory Licenses

March 1, 2014

The European Union and its member states have used compulsory licensing in a variety of settings. These are some (but not all) recent cases.

Italy

On 23 February 2005, the Autorità garante della concorrenza e del mercato (the AGCM) opened an investigation into abuses of a dominant position by refusals to license rights to active pharmaceutical products by two large pharmaceutical companies -- GlaxoSmithKline and Merck & Co Inc (Cases A363 and A364).

Merck antibiotic (Imipenem Cilastatina) patents (2005)

On June 21, 2005, the AGCM announced a compulsory license to manufacture the antibiotic Imipenem Cilastatina. Imipenem Cilastatina is a broad spectrum antibiotic used to treat infections caused by bacteria. The compulsory license allowed companies in Italy to manufacture, warehouse, and "to export the product in question to European countries where Merck has already lost all patent right."[1]

Glaxo patents on migraine drug (2006)

A February 8, 2006 decision by the AGCM announced a compulsory license to remedy the Glaxo Group's refusal to grant a licence to Fabbrica Italiana Sintetici SpA (FIS), a chemical company, for the manufacture of Sumatriptan Succinate, an active ingredient used in the production of migraine medicines.[2] The Glaxo case involved pharmaceutical supplementary protection certificates (SPCs), a type of patent extension granted by Italy. The AGCM found that Glaxo had unlawfully refused to license the right to manufacturer and export Sumatriptan Succinate to countries in Europe where the patent or SPC rights did not exist. In order to remedy the abuse, Glaxo provided FIS not only the license to Sumatriptan Succinate, but also technological know-how concerning the production process.[3] According to a February 21, 2016 Press

[1] Merck-Active Ingredients, Press Release, Pharmaceuticals: Antitrust Obliges Merck To License Manufacture Of The Antibiotic Imipenem Cilastatina, June 21, 2005. Bollettino Settimanale, Anno XV - n. 23, 27 giugno 2005, A364 - MERCK-PRINCIPI ATTIVI, Provvedimento n. 14388m pages 7-37.
[2] Bollettino Settimanale, Anno XVI - n. 6, 27 febbraio 2006, Pages 5-28.
[3] Mario Siragusa – Matteo Beretta – Matteo Bay, Competition Law in Italy: The first 20 years of law and practice. Previous version published within "Competition Laws Outside the United States", 2nd edition, ABA Section of Antitrust Law, January 2011. For a critical view of the case, see: Pablo Ibanez Colomo, Article 82 EC as a "Built-in" Remedy in the System of Intellectual Property: the Example of Supplementary

Release “Glaxo’s remedial actions following the Authority’s intervention put a rapid stop to the improper conduct and prevented delays in bringing generic pharmaceuticals to market, thus paving the way for substantial price reductions.”[4]

Merck patents on prostate cancer and male-pattern baldness drug (2007)

On 21 March 2007, the AGCM required Merck to “grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate.”[5] Finasteride is the active ingredient of a drug marketed initially under the brand name Proscar and Propecia. It is used to treat hypertrophy of the prostate, cancer of the prostate, and male-pattern baldness. The Merck royalty free compulsory licenses were remedies to Merck’s earlier refusal to license the patents to Italian manufactures of active pharmaceutical ingredients. The licenses allowed exports to “other European countries.” In announcing the compulsory licenses, the AGCM issued a statement, reproduced here:[6]

> **Press Release. Pharmaceuticals: Antitrust Authority Rules Merck Must Grant Free Licences For The Active Ingredient Finasteride**
>
> The Authority accepts and renders obligatory a commitment presented by the companies Merck & Co. Inc. and Merck Sharp & Dohme (Italia) in order to conclude the investigation launched in February 2005 into possible abuse of a dominant position. Expected price reductions for the drug to benefit consumers and the National Health System.
>
> The Merck group will be obliged to grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate. This was decided by the Italian Competition Authority when, at its meeting on 21 March 2007, it accepted and made obligatory the commitment presented by the multinational itself, thus bringing to a close without penalty the proceeding relating to abuse of a dominant position.

Protection for Pharmaceuticals in Italy. In Intellectual Property, Market Power and the Public Interest, Edited by Inge Govaere, Hanns Ullrich, College of Europe Studies, 2008.

[4] AGCM. 21 February 2006. PRESS RELEASE: Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued Granting of licence opens way for manufacture of generic migraine drugs. PROCEEDING reference n. A363, case GLAXO-PRINCIPI ATTIVI.

[5] A364 - MERCK-PRINCIPI ATTIVI, Provvedimento n. 16597, in Bollettino, Settimanale, Anno XVII - n. 11, Pubblicato sul sito www.agcm.it, Il 2 aprile 2007, Nuova versione del 4 aprile 2007, Pages 7-17.

[6] March 26, 2007. Press Release, A364 - Merck - Active Ingredients (Conclusion Of Investigation): PRESS RELEASE. PHARMACEUTICALS: ANTITRUST AUTHORITY RULES MERCK MUST GRANT FREE LICENCES FOR THE ACTIVE INGREDIENT FINASTERIDE: The Authority accepts and renders obligatory a commitment presented by the companies Merck & Co. Inc. and Merck Sharp & Dohme (Italia) in order to conclude the investigation launched in February 2005 into possible abuse of a dominant position. Expected price reductions for the drug to benefit consumers and the National Health System. http://www.agcm.it/en/newsroom/press-releases/1096-a364-merck-active-ingredients-conclusion-of-investigation.html

The corporation's commitment to remove an obstacle to the production in Italy of Finasteride and a generic version of related pharmaceuticals, among the most important drugs used in the treatment of hypertrophy of the prostate, will encourage greater competition in this market and may lead to significant reductions in retail prices and in costs for the National Health System in Italy and in other European countries.

This ruling needs to be seen in the wider context of the Authority's efforts to encourage businesses to adopt commitments aimed at improving market conditions, competition and consumer choice. In the pharmaceuticals sector in particular the Antitrust Authority's initiative is aimed at encouraging more widespread use of generic products, taking advantage of notifications from the Italian Office of Patents and Trademarks within the Ministry of Economic Development which are based on regulations governing patents in this sector. In February 2006, the Antitrust Authority had already obtained the opening up of licensing from another multinational, Glaxo, which paved the way for the manufacture of generic forms of a powerful migraine medicine, sumatriptan succinate. In this recently concluded investigation, the Authority had also obliged the Merck group, by way of an injunction, to grant licences for the manufacture of the active ingredient imipenem cilastatina which is used in the treatment of serious hospital infections.

These were cases in which the Authority had to assess the abusive nature of unjustified refusals to grant licences that were indispensable for the production of active ingredients in quantities sufficient to allow wide distribution of generic drugs, to the benefit of competition and consequently of consumers.

Rome, 26 March 2007

Germany

Compulsory licenses are often requested by defendants in litigation over infringement, and the German compulsory licensing cases can be resolved through a settlement between the parties. The public has limited access to records from such litigation, and there is less transparency than in similar proceedings in the United States, the UK or many other jurisdictions. Two cases are that are illustrative of the outcomes include the litigation between Roche and Chiron over compulsory license to patents for HIV-1 and HCV diagnostics, and a Shire request for a compulsory licenses for Fabry's disease patents held by Mount Sinai.

The Chiron patents on HIV/HCV (2000)

Roche asked a court in Germany for a compulsory license to patents held by Chiron, relating to HIV and HCV diagnostics.[7] In 2000 Roche and Chiron settled the dispute, and Chiron agreed to license its patents to Roche. Roch and Chiron signed a license agreement in May 2001, a few

[7] Citations to documents from this case, are found in US Patents Nos. 6458527, 6531276, 7205101, 7273695, 7285271, 7393949, 7408053, 7425428, 7426637, 7442525, 7527925.

weeks after the conclusion of a highly publicized trial in South Africa, where Roche was one of several large drug companies suing Nelson Mandela and the government of South Africa, over provisions regarding patents in the South Africa Medicines Act. The agreement included a clause (Article 5) obligating Roche to abandon efforts to obtain compulsory licenses to the Chiron patents. [8]

BLOOD SCREENING HCV PROBE LICENSE AGREEMENT between CHIRON CORPORATION F. HOFFMANN-LA ROCHE LTD. and ROCHE MOLECULAR SYSTEMS, INC.

BACKGROUND

WHEREAS, in consideration of and subject to the execution and delivery of the Settlement Agreement, CHIRON granted licenses to ROCHE under certain patent rights relating to HCV for use in assays for the detection of nucleic acid sequences for use in Blood Screening, subject to certain geographic and time limitations, under that certain Blood Screening HCV/HIV Probe License Agreement dated as of October 10, 2000 (the "Interim Agreement").

ARTICLE 5
OTHER ACTIONS

5.1 *Patent Validity; Enforceability.* Immediately upon the Effective Date, or as soon as possible thereafter, ROCHE shall discontinue any opposition, challenge, compulsory license application or the like with respect to the CHIRON Licensed Patents.

5.2. *Compulsory Licensing.* ROCHE covenants and agrees on behalf of itself and its Affiliates to not support any third party in seeking compulsory licensing of the CHIRON Licensed Patents in any jurisdiction. As used in this Section, "support" shall have the same meanings as in Section 7.2(b).

Signed:
CHIRON CORPORATION, Seán P. Lance, Chairman and CEO, May 22, 2001
F. HOFFMANN-LA ROCHE LTD, Heino von Prondyznski, Head of Roche Diagnostics, May 21, 2001
ROCHE MOLECULAR SYSTEMS, INC. Heiner Dreismans, President, RMS, May 9, 2001

[8] See Ex-10.315 , BLOOD SCREENING HCV PROBE LICENSE AGREEMENT between CHIRON CORPORATION F. HOFFMANN-LA ROCHE LTD. and ROCHE MOLECULAR SYSTEMS, INC. May 2001. http://www.sec.gov/Archives/edgar/containers/fix013/706539/000091205701527018/a2054786zex-10_315.htm.

Standard Tight-Head Drum patent (2004)

In 2004, the German Supreme Court determined that a compulsory license was appropriate in a case where the patent applied to a standard, and it was necessary to use the standard to serve the market.[9] The case involved an Italian manufacturer of barrels for chemical liquids. It is perhaps worth noting that the litigation in Germany came roughly at the same time that the United States Federal Trade Commission was investigating the anticompetitive conduct of Unocal in the United States, in a case involving a patent on a mandated standard for clean gasoline in California.[10] Commenting on the dispute in Germany, Alexander Harguth notes:[11]

> "An Italian manufacturer of barrels for chemical liquids argued that the patentee's refusal to grant the manufacturer a licence constituted an abuse of a market-dominating position by discriminating against the manufacturer in the face of other manufacturers to whom licences had been granted by the patentee. Indeed, a refusal of that licence would have kept the manufacturer away from a particular market. The German Supreme Court recognised that in such a situation, it is the patentee's duty to grant a licence and that, furthermore, the accused infringer may rely on a defence against an injunction requested by the patentee in patent litigation."

Orange-Book-Standard (2009)

On May 9, 2009, in a case that did not result in a compulsory license, the German Federal Court of Justice held that a defendant in a patent infringement case can use a patent holder's refusal to license as a defense from the grant of an injunction. However, the court also described a set of obligations, for the defendant, before the defense can be used to avoid an injunction being issued.

The dispute involved patents on the Orange Book standard for optical disks. Philips sued SK Kassetten GmbH & Co., in Germany, for infringement. Kassetten responded by charging Philips with an abuse of its dominant market position, by refusing to license the patents on Fair, Reasonable and Non-Discriminatory (FRAND) terms. On May 6, 2009, the German Federal Supreme Court (BGH) ruled that a refusal to license on FRAND terms could be used to avoid an injunction, if the defendant could demonstrate:

1. The defendant had made an unconditional and irrevocable offer to license on FRAND terms,
2. The patent holder had refused that offer, and had a dominant market position, and
3. The defendant had actually paid royalties to the patent holder, or placed money into an

[9] Bundesgerichtshof (BGH) of 13 July 2004, (2004) Gewerblicher Rechtsschutz und Urheberrecht 966 – Standard-Spundfass.

[10] Neela Banerjee, Unocal Is Sued by F.T.C. Over California Gas Patents, New York Times, March 5, 2003. http://www.nytimes.com/2003/03/05/business/unocal-is-sued-by-ftc-over-california-gas-patents.html.

[11] FRAND Defence in German Courts: Remedy Against Standard-Essential Patents? June 21, 2012.

account for payment.

The Court said that if a “sufficient amount” had been deposited, and if the other elements of the "compulsory license defence" are met, the court may establish that patent holder is obliged to accept the license offer.

In practice the Orange-Book standard has proved difficult to meet in the context of standards essential patent cases, and more recently, the European Commission has proposed to make it more difficult to obtain injunctions on standards relevant patents.

Shire asks German Court for compulsory licenses to Mount Sinai Fabry’s Disease Patents (2011-2)

In 2011, Shire, a Dublin based pharmaceutical company, asked a German court for a compulsory license to patents held by the Mount Sinai Medical Center. The case was settled with Mount Sinai licensing its patents to Shire. The context for the case is as follows. Mount Sinai had earlier licensed its patents for a treatment for Fabry’s disease to Genzyme Corporation, which Genzyme sold in the United States, Europe and around the world, under the brand name Fabrazyme. Shire sold a rival treatment for the same condition, in Europe, but not in the United States. In June 2009, Genzyme had serious problems with its manufacturing facilities, leading to shortages of the treatment, particularly in the United States, where Genzyme was the only supplier of the treatment for Fabry’s disease. In December of 2009, Shire filed an application with the FDA to sell Replagal, its rival treatment, in the United States.

While the shortage continued, and patients were severely rationed in the United States, Mount Sinai brought patent infringement cases against Shire in Sweden, on April 14, 2010, and in Germany, on April 20, 2014, seeking damages and injunctions.

As the Fabrazyme shortage continued, on August 2, 2010, patients in the United States asked the U.S. National Institutes of Health (NIH) to grant a compulsory license on the Mount Sinai patents. On December 1, 2010, the NIH rejected the U.S. Fabry’s patients’ request for a compulsory license in the United States, in part on the grounds that FDA test data exclusivity created an additional barrier to entry that would not be overcome by the compulsory license of the NIH funded patents.[12] While rejecting the U.S. March-In request, the NIH decision also discussed the related litigation in Europe, and reported a commitment made to the NIH to “not pursue” an injunction during an “existing or future shortage of Fabrazyme.”

> . . . since Mount Sinai's European patent equivalent to the ’804 patent (EP 1 942 189) was granted on April 14, 2010, Mount Sinai has initiated infringement actions in Germany and Sweden against Shire for its sale of Replagal. Infringement actions can be coupled

[12] National Institutes Of Health, Office Of The Director, Determination In The Case Of Fabrazyme, Manufactured By Genzyme Corporation, December 1, 2010.

with a demand for an injunction to halt use of a patented invention. In this case, a reduction in the supply of Replagal during a period of shortage of Fabrazyme would increase demand for Fabrazyme in Europe and further limit the doses available to individual patients in the US and Europe. Mount Sinai has assured us that it will not pursue an injunction against the marketing and sale of Replagal during any period of an existing or future shortage of Fabrazyme. We expect Mount Sinai and Shire to make the welfare of the patients their first priority as they resolve resolve their differences.

Mount Sinai was required by the NIH to provide periodic reports on the issues relating to the Fabrazyme shortage. On January 3, 2011, Sally Strauss, a Senior Associate General Counsel for Mount Sinai Medical Center, wrote to Ann Hammersla, Director, Division of Policy, Office of Technology Transfer, U.S. National Institutes of Health, to report that Shire planned to ask a German court for a compulsory license to its European patent.[13] On March 1, 2011, Strauss wrote to the NIH on behalf of Mount Sinai to report that "we have now been served with Shire's motion for a compulsory license for the territory of Germany."

On June 1, 2011, Mount Sinai wrote to the NIH to report that it continued to litigate its patent rights in Europe, including also a case in the UK, and that the shortage of Fabrazyme in the United States continued, and that Mount Sinai expected to file a motion opposing the German compulsory license by June 15, 2011. On July 1, 2011, Mount Sinai reported to the NIH that it had communicated to Shire that it would not pursue an injunction through September 30, 2011, and then extended this date to December 2011. On August 1, 2011, Mount Sinai wrote to the NIH, and said "With respect to the Compulsory License Proceeding in Germany, the German Federal Patent Court recently issued a notice setting a hearing date for February 14, 2012 at 9:30am."

On May 9, 2012, Mount Sinai granted Shire a non-exclusive license to the patent in connection with the on-going sales of Replagal in the European Union.

SHIRE PLC, FORM 10-Q, For the Quarterly Period ended March 31, 2012

Legal and other proceedings

Mt. Sinai School of Medicine of New York University ("Mt. Sinai") initiated lawsuits against Shire in Sweden on April 14, 2010, and in Germany on April 20, 2010, alleging that Shire's enzyme replacement therapy ("ERT") for Fabry disease, REPLAGAL, infringes Mt. Sinai's European Patent No. 1 942 189, granted April 14, 2010. Mt. Sinai sought injunctions against the use of REPLAGAL in these jurisdictions until expiration of the patent. Mt. Sinai has been granted Supplementary Protection Certificates ("SPC") in respect of the patent in certain EU countries (including Sweden and Germany) which, where granted, extends the patent until August 2016. Where no SPC has been granted, the patent expires November 2013.

[13] January 3, 2011 Letter of Sally Strauss, Senior Associate General Counsel, Mount Sinai Medical Center, to Ann Hammersla, Director, Division of Policy, Office of Technology Transfer, U.S. National Institutes of Health.

Shire filed an opposition against Mt. Sinai's patent before the European Patent Office ("EPO") on July 23, 2010, and commenced invalidity proceedings in the UK on December 8, 2010. Mt. Sinai has counterclaimed alleging infringement in the UK proceedings.

On May 9, 2012, Shire and Mt. Sinai agreed to settle all proceedings in connection with the validity and infringement by REPLAGAL of Mt. Sinai's European Patent No. 1 942 189. The parties agreed to discontinue all court and related proceedings in this dispute, and Mt. Sinai has granted Shire a non-exclusive license to the patent in connection with the on-going sales of REPLAGAL in the EU.

UK

Virgin Atlantic v Premium Aircraft (2009)[14]

In 2009, in the context of a proceeding regarding an injunction for patents held by Virgin Atlantic on the design of luxury aircraft seats,[15] a UK court provided Premium Aircraft a narrow compulsory license to use the infringing patents, subject to payment of damages. In the December 2009 decision, the court found the patents valid and infringed upon, and granted a partial injunction against their use, but provided for a "carve out" of the injunction for the sale and use of the infringing seats by Delta Airline, for some flights that were not in direct competition with Virgin Airlines. In granting the "carve out" to the injunction, the Judge wanted to avoid a sanction that was "grossly disproportionate" to the harm caused the patent holder. The judge gave five reasons for permitting infringement for this limited use, including "slight weight" to "the potential effect on employment," and a greater weight on the fact "that the infringing seats will not be used in competition with Virgin Atlantic."

IPCOM v Nokia (2012)

In 2012, the UK denied an injunction to IPCom, allowing Nokia to infringe a valid smartphone patent. As precedent, the court relied upon an 1894 case, Shelfer v City of London Electrical Lighting Co., which held that in some cases, "damages in substitution for an injunction may be given."[16] In the IPCom case, the UK Court was influenced by an earlier December 10, 2009

[14] Virgin Atlantic Airways Limited v Premium Aircraft Interiors UK Limited [2009] EWCA Civ 1513, 21 December 2009.

[15] For a discussion of the patent claims, see: Annsley Merelle Ward, The Not-So Friendly Skies: Virgin Atlantic v Contour et al (Part I). IPKat. Friday, 10 August 2012. For a report on a subsequent ruling on the infringement claims, see: Jeremy Hodges, Virgin Atlantic quits plane-seat production after patent defeat, Live Mint, July 4, 2013. http://ipkitten.blogspot.com/2012/08/the-not-so-friendly-skies-virgin.html.

[16] Court of Appeal. Shelfer v City of London Electric Lighting Company. April 19, 1894. "There are however, cases . . . in which damages may be awarded in substitution for an injunction. . . In my opinion, it may be stated as a good working rule that --

(1) If the injury to the plaintiff's legal rights is small,
(2) And is one which is capable of being estimated in money,
(3) And is one which can be adequately compensated by a small money payment,
(4) And the case is one in which it would be oppressive to the defendant to grant an injunction: --

"FRAND Declaration" by IPCom, offering to license its standards essential patents on Fair, Reasonable and Non-discriminatory terms. IPCom had made the 2009 declaration in order to avoid fines from the European Commission competition authorities. In denying the injunction, the UK judge said "You are willing to give a licence. Nokia wants to get a licence. You cannot agree on the terms. They will be determined."[17] Nokia issued this statement:

> "Nokia is pleased that the UK High Court has finally dismissed IPCom's attempts to obtain an injunction. Mr Justice Roth has confirmed that IPCom must abide by the commitments that it made to the European Commission, and cannot seek injunctions under standard-essential patents against companies such as Nokia who are prepared to take a licence on fair, reasonable and non-discriminatory terms."[18]

European Commission Compulsory Licenses on Standards Essential patents

The European Commision has broad authority to grant compulsory licenses, as remedies to anticompetitive practices.

Microsoft Corp. v Commission of the European Communities (2007), Case T-201/04

One example was Microsoft case T-201/04, which, among several issues, involved mandatory licensing of interoperability information. The European Commission found Microsoft abusing a dominant position, and required Microsoft to grant a licence for "the use of a product covered by intellectual property rights,"[19] addressing specially "the refusal by Microsoft to supply its competitors with 'interoperability information' and to authorise the use of that information for the purpose of developing and distributing products competing with Microsoft's own products on the work group server operating systems market."[20] One of the more contentious areas of the case involved the Commission mandated prices for access to the interoperability information.[21]

MathWorks (2012-)

On February 29 2012, the European Commission initiated formal antitrust proceedings in case COMP/C-3/39.840 – The MathWorks. The Mathworks is a privately held firm, based in the United States, that produces a number of software products, including MATLAB, an

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then damages in substitution for an injunction may be given."

[17] Florian Mueller, UK High Court denies a patent injunction against Nokia in light of a FRAND commitment, FOSS Patents, May 30, 2012.

[18] Electronista Staff, IPCom patent injunction versus Nokia denied in UK, May 30, 2012. http://www.electronista.com/articles/12/05/30/patent.withdrawn.in.germany.all.injunctions.denied/

[19] Case T-201/04, Microsoft Corp. v Commission of the European Communities, Summary of the Judgement.

[20] Summary of the Judgement in case T-201/04. European Commission Legal Service.

[21] See, for example: Microsoft Statement on European Commission Action on Protocol Pricing. March 01, 2007 http://www.microsoft.com/en-us/news/press/2007/mar07/03-01pricingprotocolpr.aspx.

Simulink, two leading programs used by scientists for data analysis and simulations. The Commission will determine if The Mathworks "has refused, and still is refusing, to provide competitors with certain software licenses and/or interoperability information in relation to its Simulink and MATLAB product families." The Commission will determine if such refusals to license have taken place, and if such a refusal is "an Infringement of Article 10 of the Treaty on the Functioning of the European Union and Article 54 of the EEA Agreement[22],[23] and fashion a remedy, which will likely include a compulsory license. The press release announcing the investigation[24] highlighted the Microsoft case as a precede noting the importance of "allowing for reverse-engineering for interoperability purposes."

Samsung - Enforcement of UMTS standards essential patents (2012-)

On January 31, 2012, the European Commission announced an investigation into Samsung's enforcement of standards essential patents (SEPs). The press release raise the issue of Samsung's efforts to obtain injunctions on patent rights that were essential to implement European mobile telephony standards.

> **Commission Press Release, March 1, 2012.**
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> In 2011, Samsung sought injunctive relief in various Member States' courts against competing mobile device makers based on alleged infringements of certain of its patent rights which it has declared essential to implement European mobile telephony standards. The Commission will investigate, in particular, whether in doing so Samsung has failed to honour its irrevocable commitment given in 1998 to the European Telecommunications Standards Institute (ETSI) to license any standard essential patents relating to European mobile telephony standards on fair, reasonable and non-discriminatory (FRAND) terms. . . .
>
> In line with the Commission's Guidelines on standardisation agreements (see IP/10/1702 and MEMO/10/676), standard setting organisations, including ETSI, require the owners of patents that are essential for the implementation of a standard to commit to license these patents on FRAND terms. This commitment serves to ensure effective access to the standardised technology. Such commitments were given to ETSI by many patent holders, including Samsung, when the third generation ("3G") mobile and wireless telecommunications system standards were adopted in Europe.

On October 27, 2013, the Commission requested comments from proposals by Samsung to resolve the dispute:[25]

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[22] http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39840

[23] See also: Glyn Moody, EC Defends Interoperability, but Misses Bigger Picture, Computerworld, UK March 2, 2012.

[24] Antitrust: Commission opens proceedings against MathWorks, March 1.2012. http://europa.eu/rapid/press-release_IP-12-208_en.htm

[25] http://europa.eu/rapid/press-release_MEMO-13-910_en.htm

"Samsung commits not to seek injunctive relief in the European Economic Area wi regard to all its SEPs which read on technologies implemented in smartphones an tablets (Mobile SEPs) against any company which agrees to and complies with a particular licensing framework. The licensing framework consists of: (i) a negotiatic period of up to 12 months and (ii) a third party determination of FRAND terms by either a court or arbitrator, as agreed by the parties. If the parties cannot agree on either submitting to court or arbitration, the parties will have to submit to arbitration

39985 Motorola - Enforcement of GPRS standard essential patents; and 39986 Motorola - Enforcement of ITU/ISO/IEC and IEEE standard essential patents

On April 3, 2012, the European Commission opened two related investigations into Motorola's use of injunctions to enforce standards relevant patents.

Antitrust: Commission opens proceedings against Motorola

Brussels, 03 April 2012

. . .

Following complaints by Apple and Microsoft, the Commission will investigate, in particular, whether by seeking and enforcing injunctions against Apple's and Microsoft's flagship products such as iPhone, iPad, Windows and Xbox on the basis of patents it had declared essential to produce standard-compliant products, Motorola has failed to honour its irrevocable commitments made to standard setting organisations. In these commitments, Motorola engaged to license those standard-essential patents on fair, reasonable and non-discriminatory (FRAND) terms. The Commission will examine whether Motorola's behaviour amounts to an abuse of a dominant market position prohibited by Article 102 of the Treaty on the Functioning of the EU (TFEU). In addition, the Commission will also assess the allegation by both Apple and Microsoft that Motorola offered unfair licensing conditions for its standard-essential patents in breach of Article 102 TFEU.

. . .

On May 6, 2013, the Commission published a "Statement of Objections to Motorola Mobil on potential misuse of mobile phone standard-essential patents."

In industries such as the IT sector, industry standards are key to ensuring interoperability and fostering innovation. They bring benefits to consumers and businesses. However, once a technology has been chosen and the standard has been set, it is important that the standard is accessible to all interested parties. In order to ensure such access and to prevent patent hold-up, standard-setting organisations generally require that members commit ex ante to license their standard essentia

patents (SEPs) on Fair Reasonable and Non-Discriminatory (FRAND) terms.

Against this backdrop, the Commission is concerned that the use of injunctions can be anti-competitive. In this case, the Commission considers at this stage that recourse by Motorola Mobility to injunctions on the basis of FRAND-encumbered SEPs distorted the negotiation process for a FRAND licence with Apple – a willing licensee. Hold-ups of this kind can ultimately lead to less consumer choice with regard to interoperable products and less innovation.

In the case at hand, the Commission is of the preliminary view that Apple's willingness to enter into a FRAND licence manifested itself in particular by its acceptance to be bound by a German court's determination of a FRAND royalty rate. The Commission's preliminary view is that the acceptance of binding third party determination for the terms of a FRAND licence in the event that bilateral negotiations do not come to a fruitful conclusion is a clear indication that a potential licensee is willing to enter into a FRAND licence. This process allows for adequate remuneration of the SEP-holder so that seeking or enforcing injunctions is no longer justified once a potential licensee has accepted such a process.

By contrast, a potential licensee which remains passive and unresponsive to a request to enter into licensing negotiations or is found to employ clear delaying tactics cannot be generally considered as "willing".

In addition, in the Commission's preliminary view, the fact that the potential licensee challenges the validity, essentiality or infringement of the SEP does not make it unwilling where it otherwise agrees to be bound by the determination of FRAND terms by a third party. In the case at hand, Motorola required clauses that prohibited such challenges by Apple, even after Apple had agreed to be bound by a third party determination of the FRAND terms. The Commission's preliminary view is that it is in the public interest that licensees should be able to challenge the validity, essentiality or infringement of SEPs.

The Commission also distinguished and distanced its policy from the 2009 “Orange Book” ruling the German Supreme Court.

What is the relevance of the so-called German "Orange Book" case-law on injunctions?

The 2009 "Orange Book" ruling of the German Supreme Court established that a potential licensee can raise a competition law defence against an application for an injunction by showing that (i) it has made an unconditional offer to license under terms that cannot be rejected by the patent-holder without abusing its dominant position, and (ii) it actually acted as if had entered into a valid patent licence. The Supreme Court's ruling did not specifically relate to SEPs. The Commission's preliminary view is that an interpretation of that ruling whereby a willing licensee is essentially not entitled to challenge the validity and essentiality of the SEPs in question is potentially anti-competitive.