9 Patent Thickets and Refusals to License in the Life Sciences in Japan - Legal Remedies at the Interface between Patent and Competition Law(*)

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Concerns have been expressed on the growing number of patents in the life sciences. High numbers of patents might cause "patent thickets" and will increase the risk that one of the patentees will refuse to grant a license. These two phenomena might ultimately block R&D and commercialization in the biomedical industry. Is there indeed a patent thicket in the biomedical field in Japan? And are there cases of refusals to license? If so, what are the potential remedies?

This kind of problems is not necessarily solved by way of legislative reforms. Legal instruments which already exist in the patent act (e.g. research exemption, awards for non-exclusive licenses) and voluntary patent licensing schemes (e.g. patent pools, clearinghouses) might be more appropriate. In addition, there might be a need to further clarify, strengthen or stimulate these instruments. Some of these solutions, such as for instance patent pools are common in other sectors, but have not been established in the life sciences. Intermediaries, such as clearinghouses, already exist, but their role on the market for technology exchange might be further stimulated by policy initiatives.

Both the problems and possible remedies will be reviewed from an innovation policy perspective, in particular from the so-called "open innovation"-paradigm.

I Introduction

Japan aims at becoming a 'true' "intellectual property based nation". (*1) In this respect, the Japanese government has introduced many new legislative changes and launched various policies aimed at industry, universities and research institutes. For the scope of this report it is particularly interesting that the life sciences have been identified as one of the priority areas in Japan's Science and Technology (S&T) Basic Plan issued in 2006 (hereinafter 3rd S&T basic Plan).(*2)

It is widely known that patents are critical for the life sciences sector. Only in the pharmaceutical industry managers do rate patents as more effective than other means of profiting from innovation. It is estimated that over one half of the worldwide value of patents accrues a small number of large pharmaceutical companies. (*3) Patents have played this role supporting different innovation models. (*4) For long, most companies adopted a form of "closed innovation" characterized by focusing on internal ideas, internal research and development (R&D) and control of intellectual property (IP) (especially patents). This approach favored vertically integrated companies generating their own ideas, developing them, building them, marketing them, distributing them, servicing them, financing them, and supporting them on their own. However, nowadays the distribution of knowledge has spilled beyond the knowledge held by big firms' central research laboratories, leading to pools of knowledge shared by companies, customers,

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(*1) See for instance Intellectual Property Policy Headquarters (2003), *Strategic Program for the Creation, Protection and Exploitation of Intellectual Property*, July 8, 2003, English Translation, available at http://www.kantei.go.jp/foreign/policy/titeki/kettei/030708f_e.html.

(*2) Government of Japan (2006), Science and Technology Basic Plan, English Translation, available at http://www8.cao.go.jp/cstp/english/basic/3rd-BasicPlan_06-10.pdf. For more information, see below Section II.

(*3) Bessen, J., & Meurer, M.J. (2008), *Patent Failure*, Princeton University Press, at pp. 106-109.

(*4) All the information in this paper on innovation models and the shift from "closed innovation" to "open innovation" has been derived from the work of H. Chesbrough. See Chesbrough, H., Vanhaverbeke, W., & West, J. (eds.) (2008), *Open Innovation: Researching a New Paradigm*, Oxford-New York, Oxford University Press; Chesbrough, H. (2006a), *Open Business Models: How to Thrive in the New Innovation Landscape*, Boston, Massachusetts, Harvard Business School Press; Chesbrough, H. (2003), *Open Innovation – The New Imperative for Creating and Profiting from Technology*, Boston, Massachusetts, Harvard Business School Press.

suppliers, universities, research institutes, consortia, and start-ups.

Globally, more and more companies are gradually developing towards an "open innovation model" using external ideas as well as internal ideas, and internal and external paths to market, in order to advance their technology. This different innovation model requires new business models and a different approach towards intellectual property as well. Therefore, it is essential to analyze to what extent the life sciences have responded to this changed innovation paradigm and how this has developed in Japan. Such an open way of pursuing R&D will create new opportunities and challenges. Increased industry collaborations, university-industry collaborations, clusters and consortia may result in advances in R&D which could be protected by applying for patents. It would be desirable to complement the open way of carrying out R&D with an "open attitude" regarding patents and collaborative licensing models.

Many experts express concerns on the growing number of patent applications/granted patents in the life sciences, which might cause patent thickets. A patent thicket is a situation where organizations encounter many overlapping patents held by many patent owners in the area where they are doing research, are developing products or carrying out services. Patent thickets generally develop in fields with complex products, production or research processes or in areas where many organizations compete in R&D in the same area, resulting in fragmented patent ownership. (*5) Next to the risk of patent thickets patents as such also permit their owners to refuse to grant a license. Though legitimate and inherent in the purpose and key function of patents, in some cases patent thickets and refusals to license might create a paradox and ultimately block R&D and commercialization of essential products.

These two phenomena are not unique for the life sciences but also occur in other technology fields. Both industry and governments have considered a wide variety of mechanisms to remedy situations of fragmented patent rights and overcome concerns for refusals to license by encouraging collaboration amongst different stakeholders in order to stimulate innovation, foster R&D and promote access and diffusion of technology and information. These discussions focus especially on the use of research exemptions, licensing guidelines, different voluntary collaborative licensing models (patent pools, clearinghouses), and compulsory licenses. When examining these remedies it is important to consider the balance of interests of all actors involved: the interests of the patent owners wanting to recover their investments in R&D, the interests of the technology users who would like to offer their products and services at a fair price, and the public interest related to access to medicines and health care services, high quality and reasonable prices. The fact that public health might be put at a disadvantage might lead to a different balance of interests and different outcomes of the legal analysis in the life sciences sector compared to other sectors.

Ⅱ Legal Framework

Open innovation requires active involvement and knowledge spill-over between companies, customers, suppliers, universities, research institutes, consortia and start-ups. Intellectual property rights are very important to enable this process. However, legal structures should allow for such flows and facilitate the commercialization of university inventions and transfer of knowledge. The Japanese government recognized there was a gap in the Japanese legal framework which might block effective knowledge transfer from universities to industry essential for Japan's future competitive position in the world. Thus, over the years several important legislative changes were made and different policy documents issued to stimulate public-private collaboration. First, some legislation was introduced focusing on the role of universities in this process. The most relevant acts in this regard are: the "Act for Promoting University-Industry Technology Transfer", (*6) the "National University Corporation Act", (*7) and the "Act on Special Measures for Industrial Revitalization" (*8). Second, there were some more general measures which show the importance the Japanese government attaches to intellectual property rights, such as the

(*5) Nagaoka, S., & Nishimura, Y. (2006), *An Empirical Assessment of the effects of patent thickets*, SPRU 40th Anniversary Conference - The Future of Science, Technology and Innovation Policy, September 11-13, 2006, University of Sussex, SPRU-Science & Technology Policy Research (on file with the author), at p. 2.
(*6) Government of Japan (1998), Act for Promoting University-Industry Technology Transfer, Law No. 53 of 1998.
(*7) Unfortunately there is no official English translation available of this act.
(*8) Government of Japan (1999), Act on Special Measures for Industrial Revitalization, Law No. 16 of 1999.

"Science and Technology (S&T) Basic Law",(*9) the "Basic Law on Intellectual Property",(*10) the "Strategic Program for the Creation, Protection and Exploitation of Intellectual Property", (*11) and a long-term strategic policy called "Innovation 25". (*12)

In the report, also the main provisions of the Japanese Patent Act (PA) relevant for the current examination are described and an overview of the current worldwide debate on gene patents is given, explaining that in Japan this does not seem to be the biggest cause of concern, rather than research tools. In Japan the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade, commonly called the Anti-Monopoly Act (hereinafter 'AMA') (*13) is the primary source of legislation regarding competition law and is enforced by the Japanese Fair Trade Commission (JFTC). The AMA prohibits private monopolization, undue restraints of trade, and unfair business practices, and aims at preventing excessive concentration of economic power.

The definition of private monopolization and undue restraints of trade refer to the "public interest" as a criterion to evaluate the legitimacy of a certain activity. There is however discussion as to how this term should be interpreted and it is not clear to what extent it might play a role in the JFTC assessment of licensing arrangements in the life sciences.

In order to clarify JFTC's position on the interface between patent and competition law, it has published different sets of guidelines related to the use of intellectual property rights. (*14) An overview of the main principles of the 2007 Guidelines and the 2005 Patent Pool Guidelines is provided.

Ⅲ Open Innovation

Open innovation(*15) is celebrated as the new paradigm for fostering innovation. More and more organizations move from closed innovation to open innovation or innovation networks. Open innovation has been defined as "*…the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively. Open Innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology.*"(*16)

In Japan in particular in the pharmaceutical sector large Japanese companies are engaging more and more actively in external R&D collaboration and licensing. Even though this change in attitude has been relatively slow in Japan, Japanese pharmaceutical companies can no longer lag behind in the light of globalization and the importance of innovation in the pharmaceutical sector. (*17) However, it appears that the purpose of the collaborations with Japanese universities and public research institutes is primarily to obtain leading edge scientific knowledge, whereas licenses and joint research is generally conducted with overseas biotechnology companies.

Ⅳ Patent Thickets and Refusals to License in Japan?

The increased number of patents/patent applications in the life sciences has raised concerns about the eventual emergence of patent

(*9) Government of Japan (1995), Science and Technology Basic Law, Law No. 130 of 1995, English Translation, available at http://www8.cao.go.jp/cstp/english/law/Law-1995.pdf.

(*10) Government of Japan (2002), Basic Law on Intellectual Property, Law No.122 of 2002, English Translation, available at http://www.kantei.go.jp/foreign/policy/titeki/hourei/021204kihon_e.pdf.

(*11) Intellectual Property Policy Headquarters (2003).

(*12) Government of Japan (2007), *Long-term Strategic Guidelines "Innovation 25"*, June 1, 2007, available at http://www.kantei.go.jp/foreign/innovation/innovation_final.pdf.

(*13) Government of Japan (1947), Act on Prohibition of Private Monopolization and Maintenance of Fair Trade, ActNo. 54 of 14 April 1947, Latest revision by Act No. 35 of 2005, English Translation, available at http://www.jftc.go.jp/e-page/legislation/ama/amended_ama.pdf.

(*14) JFTC (1968), *International technology Transfer Agreement Guidelines*; JFTC (1989), *Guidelines for Patent and Know-How Licensing Agreements*; JFTC (1999), *Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act*, English Translation, available at http://www.jftc.go.jp/e-page/legislation/ama/patentandknow-how.pdf.

(*15) Chesbrough et al. (2008), Chesbrough (2006a), and Chesbrough (2003).

(*16) Chesbrough et al. (2008), at p. 1.

(*17) RIETI (2004), *Report on External R&D Collaboration Survey*, Tokyo, RIETI (in Japanese) and cited by Motohashi, K. (2005), *The Changing Autarky Pharmaceutical R&D Process: Causes and Consequences of Growing R&D Collaboration in Japanese Firms*, at p. 2, available at http://www.mo.t.u-tokyo.ac.jp/seika/files/bio-paper%20(1).pdf.
and Akimoto, H. (2008), *The Future of Research and Development – Focus on the Life Science Industry*, RIETI Policy Symposium, January 11 2008, http://www.rieti.go.jp/en/events/08011101/pdf/6-1_E_Akimoto.pdf.

thickets and refusals to license or unreasonable licensing conditions, especially in the area of genetics. If there are many patents in the hands of different owners this may ultimately lead to difficulties in bargaining licenses to the patented inventions successfully (patent thicket). (*18) Every licensor will require the payment of royalties or upfront license fees, which ultimately may lead to royalty stacking. Patent thickets in genetics may disrupt further innovation, because in genetics substitutes for genetic inventions (such as patented genes) are often lacking and competitors will therefore often not be able to invent around those patents. Heller and Eisenberg suggested that this increase in patents may result in a "tragedy of the anticommons" in biomedical research. The high transaction costs and the stacking of royalties may stand in the way of an agreement. This may lead to "underuse" of the patents concerned. (*19)

There is an increase in patenting and licensing in the life sciences in Japan. There are concerns about the anti-commons problem resulting from gene patents, but especially with regard to patents on research tools. These fears concern primarily technology which had to be licensed in from the US. (*20) In an economic study coordinated by IIP on the Tragedy of the Anticommons in Japan(*21) there is no firm conclusion to what extent there is a situation of tragedy of the anticommons in Japan. However, Sumikura observes a trend among Japanese life science researchers of anxiety and discomfort in using research tools, which might also have a blocking effect. (*22)

Empirical evidence in Japan shows that overall licensing negotiations seem to run quite well. In contrast, in the pharmaceutical sector and vis-à-vis SMEs in about 20% of the cases licenses are refused. On top of this, in 40% of the cases SMEs cannot reach an agreement due to high licensing fees. (*23) Abandoning R&D projects due to refusals to license is, however, rare. In most cases, these situations are avoided by – in the end – paying high licensing fees. Nowadays Japanese pharmaceutical companies are becoming more active in licensing-in patents from overseas business ventures. Refusals to license are more common in cases where the patent owners are overseas start-up businesses, mostly US companies. (*24)

Ⅴ Legal Remedies for Patent Thickets in Japan

In this chapter the Japanese research exemption and some recent developments in this regard are described. There is no case-law available in Japan clarifying the scope of this exemption, but according to the literature it does not cover research tools. In this light various Japanese experts have proposed alternative solutions.

Also the use of licensing guidelines could serve as a way to steer away universities and companies from exclusive exploitation of patents. In this light the Council for Science and Technology Policy (CSTP) has introduced two sets of guidelines. (*25) There is however need for more commitment to these guidelines, which could also be enforced by funding agencies granting research funds on the condition of

(*18)Shapiro, C. (2001), 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting', in Jaffe, A., Lerner, J., Stern, S. (eds.), *Innovation Policy and the Economy*, Cambridge, MIT Press, 2001, Vol. I, 119-150, available at http://haas.berkeley.edu/~shapiro/thicket.pdf.

(*19) Heller, M.A (1998), 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets', *Harvard Law Review*, *111*, 621-688 and Heller, M. A., & Eisenberg, R. (1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science,* 280, 698-701, available at http://www.sciencemag.org/cgi/reprint/280/5364/698.pdf.

(*20) Motohashi, K. (2003), *Japan's Patent System and Business Innovation: Reassessing Pro-patent Policies*, RIETI Discussion Paper Series 03-E-020, at p. 26, available at http://www.rieti.go.jp/jp/publications/dp/03e020.pdf.

(*21) Nagaoka et al. (2005), *Analysis of Various Issues Concerning the "Tragedy of the Anticommons"*, Tokyo, IIP (in Japanese), English Summary, *IIP Bulletin* 2006, Study No. 6, 44-49, available at http://www.iip.or.jp/e/summary/pdf/detail2005/e17_06.pdf, at p. 44 ('2005 Tragedy of the Anticommons study').

(*22) Sumikura (2007), 'A Consortium for Enhanced Access to Patented Research Tools: Japanese Policy and Proposal of a Novel Scheme', PICMET 2007 Proceedings, 5-9 August, Portland, at p. 697-698 and Sumikura, K. (2006), *Intellectual Property Rights Policy for Gene-Related Inventions – Toward Optimum Balance Between Public and Private Ownership*, Conference paper for "The Role of Intellectual property Rights in Biotechnology Innovation", 2006, at pp. 6-7.

(*23) Motohashi (2003), at pp. 16-17.

(*24)Motohashi (2003), at pp. 27 and 29 and Personal communication Mr. Morioka, Director of the R&D Division of JBIC, December 4, 2008.

(*25) CSTP (2007), *Guidelines for Facilitating the Use of Research Tool Patents in the Life Sciences*, English Translation, available at http://www8.cao.go.jp/cstp/siryo/haihu64/siryo1-2-e.pdf and CSTP (2006), *Guidelines for Research Licenses for Intellectual property Rights Stemming From Government-Funded Research and Development at Universities, etc.*, English Translation, available at http://www8.cao.go.jp/cstp/siryo/haihu55/siryo3-2-e.pdf.

serious commitment to the guidelines.

Furthermore, different national and international advisory organs(*26) and experts(*27) have suggested that collaborative licensing models could be used in order to solve the problem of patent thickets in the life sciences. Examples of such collaborative models are patent pools and clearinghouses. However, none of these authorities precisely defined what type of pool or clearinghouse would be optimal in the life sciences and how it should function in practice. In view of the variety of existing models and the broad interpretation of the clearinghouse concept, it is important to be more precise and to define different types of patent pools(*28) and clearinghouses(*29), the desirable functions, the institutional framework and the features.

A patent pool has been commonly defined as an agreement between two or more patent owners to license one or more of their patents to one another and as a package to third parties who are willing to pay the royalties associated, either directly by patent owners to licensees or, indirectly, through a new entity specifically set up for the pool administration. Patent pools thus allow interested parties to gain access to all patents to work an invention with one single license, a so-called "one-stop-license", rather than obtaining licenses from each patent owner individually. The analysis of the patent pools in the report includes an overview of the benefits and risks and an examination of the question what could be the reason that patent pools are common in other technology sectors (consumer electronics, telecommunications and semiconductors), but companies in the area of biotechnology and pharmaceuticals seem to be rather reluctant to use this licensing instrument. A number of brief case studies of the Pachinko-pool, (*30) the MPEG2-pool, the 3G-platform, the ULDAGE-pool and the SARS-pool complement this analysis.

The term clearinghouse is interpreted in a very broad way and is used in relation to almost any mechanism whereby providers and users of goods, services and information are matched. (*31) Five types of clearinghouses can be distinguished:

(*26) Australian Law Reform Commission (2004), *Gene Patenting and Human Health*, Sydney, Australian Law Reform Commission, Discussion Paper No. 68, 2004, available at http://www.alrc.gov.au, Human Genome Organisation (2003), *Statement on the Scope of Gene Patents, Research Exemption and Licensing of Patented Gene Sequences for Diagnostics*, available athttp://www.hugo-international.org/img/ip_gene_2003.pdf ; Nuffield Council on Bioethics (2002), *The Ethics of Patenting DNA*, London, Nuffield Council on Bioethics, Discussion Paper No. 932002, 2002, available at http://www.nuffieldbioethics.org OECD (2006), *Guidelines for the Licensing of Genetic Inventions*, Paris: OECD, para. 41, available at http://www.oecd.org/dataoecd/39/38/36198812.pdf.

(*27) Gold, E.R., 'Biotechnology patents: strategies for meeting economic and ethical concerns', *Nature Genetics*, *30,* 359, Graff, G.D., Cullen, S.E., Bradford, K.J., Zilberman, D., Bennett, A.B. (2003), 'The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology', *Nature Biotechnology*, *21*, 989-995, at 994-995; Graff, G.D., Zilberman, D. (2001), 'Towards an Intellectual Property Clearinghouse for Ag-Biotechnology. An Issues Paper', *IP Strategy Today*, *3*, 1-38, at 10-14; Krattiger, A.F. (2004), 'Financing the Bioindustry and Facilitating Biotechnology Transfer', *IP Strategy Today*, *8*, 1-45, at 19-23, Nicol, D. (2008), 'Navigating the molecular diagnostic patent landscape', *Expert Opinion on Therapeutic Patents*, *18*, 461-472 and Van Overwalle, G., van Zimmeren, E., Verbeure, B., Matthijs, G. (2006), 'Models for facilitating access to patents on genetic inventions', *Nature Reviews Genetics*, *7*, 143-148, at 145-147.

(*28) For a more complete analysis of the features of patent pools, see for instance Verbeure, B. (in press), 'Patent Pooling for Gene-based Diagnostic Testing: Conceptual Framework', in Van Overwalle, G. (ed.), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearing Houses, Open Source Models and Liability Regimes*, Series: Cambridge Intellectual Property and Information Law (No. 10), Cambridge: Cambridge University Press and the references cited there.

(*29) For a more complete analysis of the features of clearinghouses, see van Zimmeren, E. (in press), 'Clearinghouse Mechanisms in Genetic Diagnostics: Conceptual Framework', in Van Overwalle, G. (ed.), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearing Houses, Open Source Models and Liability Regimes*, Series: Cambridge Intellectual Property and Information Law (No. 10), Cambridge University Press and van Zimmeren, E., Verbeure, B., Matthijs, G., & Van Overwalle, G. (2006), 'A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions', *WHO Bulletin*, *84*, 352-359.

(*30) JFTC (1997), Recommendation decision handed down to ten companies including Sankyo Co., Ltd. in accordance with Article 3 AMA., English Translation provided by IIP. Parallel to the Pachinko-pool there was a so-called "Pachislo-pool". In a procedure before the Tokyo District Court the plaintiff argued that this pool was comparable to the Pachinko-pool and violated the AMA. The Tokyo District Court held that the Pachislo-pool does not have non-competition provisions and did not prevent new entry to the market. This view was later confirmed by the Tokyo High Court. See: Tokyo District Court, Aruze Corporation vs. Sammy Corporation and Japan Electric Game Machine Patent Co. Ltd., Case No. 2000 (WA) 3563, March 12, 2002, English Translation provided by IIP and Tokyo High Court, Aruze Corporation vs. Sammy Inc. and Japan Electric Game Machine Patent Co. Ltd., Case No. 2002 (ne) 4085, English Translation provided by IIP.

(*31) Krattiger (2004), at p. 20.

information clearinghouses, technology transfer clearinghouses, open access clearinghouses, standard licenses clearinghouses, and royalty collection clearinghouses. For all these types examples are sought in the life sciences in Japan. Again brief case studies are included of the National Center for Industrial Property Information and Training (INPIT), (*32) J-STORE,(*33) the Single Nucleotide Polymorphisms (SNP) Consortium, (*34) Science Commons, (*35) the proposal for a consortium for research tools, (*36) the Japan Biological Informatics Consortium (JBIC), (*37) and the Japanese Society for Rights of Authors, Composers and Publishers (JASRAC)(*38). For a clearinghouse to become effective, the main requirement is that it is collects a critical mass of valuable(*39) technologies available for licensing out. It should market this technology efficiently and promote fair, reasonable and non-discriminatory licensing practices. Moreover, it is important to continuously grow the technology base.

An important difference between clearinghouses and patent pools is that in case of a clearinghouse there is no need for agreements between the patent owners. From a competition law perspective this substantially weakens the risk of collusion and price fixing by competitors.

Patent pools and clearinghouses are often presented as a remedy for patent thicket problems in electronics, telecommunications, semiconductors and potentially also the life sciences, but they may also play a pro-active instrumental role in the light of open innovation initiatives.

Ⅵ Legal Remedies for Refusals to License in Japan

The analysis on refusals to license starts with reiterating the examination regarding the research exemption and licensing guidelines in the previous chapter and explaining their limited role with regard to refusals to license. However, there are some ways how this could be improved. Also patent pools and clearinghouses are not of much use to remedy the refusal to license problem, as these are largely voluntary mechanisms.

The Japanese PA allows for "arbitrary awards granting non-exclusive licenses" to third parties without the authorization of the patent owner. Such awards have effects comparable to compulsory licenses more common in other countries. These awards were one of the key issues discussed in the Structural Impediments Initiative (SII), a series of bilateral talks between the U.S. and Japan from 1989-1994 during which the US. government asked Japan to commit to strengthening its patent protection and stop using the compulsory licensing clause. Since then, in Japan the arbitrary award clauses have never been used even though apparently there have been requests for such an award.

There are three types of awards granting non-exclusive licenses: awards granting non-exclusive licenses for non-working (Article 83), awards granting non-exclusive licenses for dependent inventions (Article 92) and awards granting non-exclusive licenses for the public interest (Article 93). For the scope of this report, especially the latter is relevant. The Industrial Property Council defined in its implementing guidelines(*40) that cases where the working of the

(*32) http://www.inpit.go.jp/english/index.html

(*33) http://jstore.jst.go.jp/EN/

(*34) For more information, see http://snp.cshl.org and Holden, A.L. (2002), 'The SNP Consortium: Summary of a Private Consortium Effort to Develop an Applied Map of the Human Genome', *BioTechniques*, 32, S22-S26.

(*35) For more information, see http://sciencecommons.org/projects/licensing/.

(*36) Sumikura (2007); Sumikura (2006) and Morioka, H. (2006), 'Concerning the consideration-free license for patented research tools or the possibility of a patent pool', *IIP Forum* (Japan), *64*, 32-41 (in Japanese), English working machine translation provided by IIP.

(*37) http://www.jbic.or.jp/bio/english/

(*38) See http://www.jasrac.or.jp/, personal communication Mr. Imamura, Meiji University, December 16, 2008, and personal communication JASRAC, December 17, 2008. For more information on the legal framework, see the Law on Management Business of Copyright and Neighboring Rights (Government of Japan (2000), Law No. 131 of November 29, 2000, lastly amended by Law No. 154 of December 3, 2004), the Law on Intermediary Business concerning Copyrights (Government of Japan (1939), Law No. 67 of April 5, 1939, lastly amended by Law No. 160 of November 22, 1999 and repealed) and the Articles of Association of JASRAC, April 1, 2008.

(*39) There is always a risk that patent owners will only entrust their "lemons" to the clearinghouse, see Akerlof, G. (1970), 'The Market for Lemons: Qualitative Uncertainty and the Market Mechanism', *Quarterly Journal of Economics*, *84*, 488-500.

(*40) Ministry of Economy, Trade and Industry, Industrial Property Council (1997*), Implementing Guidelines of the System of Awarding Non-exclusive Licenses* (Saitei Seido no Unyo youryo), established on December 1, 1975 and lastly revised on April 24, 1997, provisional translation prepared by IIP.

patented technology is "particularly necessary for the public interest" could be cases where working is particularly needed in areas relating directly to the lives of citizens, such as public health. However, we should not forget that Article 93 contains the wording "particularly necessary for the public interest". This terminology is used explicitly in order to limit the applicability of this provision in accordance with the agreements within the SII. In the implementing guidelines also the procedure for the award of non-exclusive licenses is described. Even though the procedure is called 'arbitration', the described procedure does not appear to be a 'true' arbitration procedure, which could be improved by including the Japan Intellectual Property Arbitration Center (JIPAC) in the procedure.

The SII does leave more leeway for compulsory licenses granted in case of anti-competitive practices, that is, based on competition law. In Japan a mere refusal to license IP rights is generally considered as "the exercise of rights" (Article 21 AMA) falling outside the scope of the AMA, unless the company would have employed inappropriate measures and the behavior would amount to private monopolization or unfair trade practices. In principle it is however possible that the JFTC would conclude that an IP owner who unilaterally refuses to provide a license to another firm which consequently faces difficulties in doing business because of the essential nature of the IP, would violate the provisions on private monopolization or an unfair trade practice, that is a refusal to deal. This is also briefly explained in the 2007 Guidelines of the JFTC.

Until now there is no case-law holding a genuine unilateral refusal to license as being against the AMA. Nonetheless, in 2005 the JFTC started an investigation against Sony Music Entertainment (Japan) Inc. and 4 other companies (Avex Network Inc., Toshiba EMI Ltd., Universal Music K.K., and Victor Entertainment, Inc.) who according to the JFTC violated Section 19 AMA and Item 1 (1) of the Designation of Unfair Trade Practices as they colluded by refusing licenses to operators who would not entrust the Chaku-Uta service to Label Mobile Inc. They did not have an objective justification for this refusal. Even though, this case is an example of a collateral refusal to license and the outcome of the case is still uncertain, the final decision may give some more indications as to how refusals to license are assessed by the JFTC.

Thus, for now it is uncertain to what extent the AMA would be able to prevent companies in the pharmaceutical and biotechnology industry from refusing to license their patents, even when the underlying technology could be classified as an "essential facility" needed in order to allow for further innovation and competition on a secondary market. The JFTC has established a Working Group related to New Technologies, which is also dealing with refusals to license. Maybe the outcome of the discussions will shed some more light on the optimal approach towards refusals to license.

Ⅶ Conclusions

Open innovation is becoming more important as a policy in the life sciences in Japan to deal with all kinds of challenges. No longer are companies satisfied by the internal knowledge base, but they collaborate with other companies, including start-ups, universities and public research institutes. They use bilateral research collaborations, research consortia, in- and out licensing and spin-offs and spin-ins as ways to transfer technology and develop new ideas.

This open and collaborative environment might create further opportunities and a platform for further debate on licensing practices which are most appropriate in such a context. While setting up research collaborations and consortia, it is desirable to think pro-actively about IP management. It is to be expected that in particular if many parties participate in such research projects, thickets of patent rights might emerge. Collaborative licensing models facilitating multiple transactions and lowering transaction costs might thus be a logical component of open innovation initiatives.

In view of the limited number of Japanese bioventures most new technologies have to be purchased or licensed-in from overseas. In those licensing negotiations Japanese companies often experience difficulties with regard to getting effective access to research tools for a reasonable price. And even if for now there is not much empirical evidence that R&D is obstructed by patent thickets, due to the emergence of new complex technologies and research areas such as RNAi, pharmacogenomics, synthetic biology, etc., we cannot exclude that such phenomena will arise in the future.

In dealing with patent thickets and refusals to license a whole spectrum of remedies is available at the interface between patent and competition law. Some of these remedies include

explicit references to the role of the public interest. Other remedies will inherently require a balancing of the interests of the patent owner to recoup its investments, the private interests of the technology users, the interests of the society in terms of innovation and dissemination of the technology and public health.

Patent pools and clearinghouses have been stimulated by the Japanese government as a pro-innovation instrument to deal with situations of multiple patents held by multiple patent owners. However, these mechanisms are voluntary and until now there are not many examples in the life sciences. It might be desirable to further strengthen the debate in this area and emphasize the opportunities of such models in the light of open innovation.

Most of the suggestions in this report do not require complex and time-consuming legislative revisions, but rather a change in attitude and practices that translates the open way of innovation in an open way of transferring knowledge through responsible IP management. Choosing this path will not be the line of least resistance and will require collaboration between the Government's Intellectual Property Headquarters, the JPO, the JFTC, the CSTP, the JST, all ministries concerned and consultation of the relevant stakeholders. In the end, it will prove worth the effort of smoothing the way for a priority area like the life sciences optimizing the opportunities offered by open innovation and balancing the interests of all the stakeholders concerned.