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DIRECTORATE FOR FINANCIAL, FISCAL AND ENTERPRISE AFFAIRS

COMPETITION POLICY, INTELLECTUAL PROPERTY, AND BIOTECHNOLOGY: DOCTRINAL AND INSTITUTIONAL PERSPECTIVES

DOJ/FTC Submission

Executive Summary

1. Patents have played a central role in the growth of the biotechnology sector. Like other industries in which patents, research and development, and rapid advancements in science determine commercial success, the biotechnology sector poses formidable tasks for competition policy authorities. In addressing issues in this sector, competition agencies must:

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5. To a large degree, this paper summarises recent work of the U.S. Department of Justice (DOJ)

skills. Not only must a patent office recruit and retain skilled specialists, but the office also must afford examiners sufficient time to undertake a proper inquiry, especially the review of prior art.

11. *Robust Pre-Issuance Examination Procedures*. Beyond providing appropriate resources, a rights-granting organisation can establish procedures that discourage the issuance of weak patents. Possible means to this end include disclosure requirements that compel applicants to provide, at the request of examiners, more information, and engaging a second examiner to perform a "second-pair-of-eyes" review for certain applications.

12.

18. *Ex Post Assessments of Past Interventions*. Substantial levels of uncertainty can accompany decisions about the application of competition policy principles in dynamic, innovation-driven industries. A valuable means for informing future decisions is to assess the affect of past policy choices. Routine, systematic efforts by the competition authority to perform its own studies or engage external consultants to conduct evaluations can provide valuable guidance about the choice of future enforcement approaches.[12]

19. *Increasing the Number of Professional Staff with IP Expertise*. One way to increase the competition agency's knowledge base is to hire additional attorneys or economists with expertise in intellectual property. For example, a competition agency might consider expanding its complement of patent lawyers.

3.2 Improving the Interdisciplinary Dialogue

20. The activities of many government institutions other than competition policy agencies affect competition. A major challenge for competition policy authorities today is to build relationships with other government bodies whose decisions directly or indirectly influence the competitive process significantly.[13] CP and IP authorities would likely benefit from sustained interdisciplinary cooperation, much in the way that CP agencies have developed stronger institutional relationships with other government bodies, such as sectoral regulators. Increased cooperation would serve to increase the awareness of policymaking interdependencies and to pursue policy improvements that raise the capacity of CP and IP to promote innovation.

4. Selected Intellectual Property Licensing Issues

21. The following discussion focuses on selected issues raised in the request for submissions.

4.1 Patent Infringement Research Exemption

22. The scope of the research exemption from patent infringement liability in the United States is quite narrow.[14] The exemption is a judge-made rule that the courts have applied infrequently, only in limited circumstances where a patented device is used "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[15] Research institutions are neither automatically granted nor denied an exemption under existing law. Whether such institutions are outside the class of potential infringers, will depend on both the "legitimate business" of the institution and the *de minimise* nature of the technical infringement.[16]

23. Whether, from a competition standpoint, universities should be immune from liability when their unauthorised conduct involves research and development is a matter of debate in the United States, as demonstrated by panellists' discussions during the Hearings.[17] Some Hearing participants believed that under current law the research exemption is unavailable to most institutions in the United States because their "legitimate business" is research.[18] Those in favour of a more robust exemption propose extending the exemption to activities beyond "idle curiosity," such as research efforts aimed at "design-around" activity or patent improvements, or the use of a patented research tool to create an unrelated product (in the biotech industry, for example, gene fragments might be used to produce an end product, such as therapeutic proteins or genetic diagnostic tests).[19] Many participants agreed that an exemption is appropriate when research asks how or if an invention works, but there was no consensus in favour of an exemption beyond this inquiry.[20]

24. The National Research Council of the National Academies issued a report entitled, "A Patent System for the 21st Century," in April 2004 that states some research uses of patented inventions should be provided limited protection from infringement liability.[21] The Council encourages Congress to consider

appropriate targeted legislation and the federal government to assume liability for patent infringement arising from federally sponsored research in private universities.[22] The Council states that a recent Supreme Court ruling shields state universities from damage awards in patent infringement suits.[23]

4.2 Reach-through Licensing Agreements

25. Reach-through licensing agreements allow the owner of a patent on a research tool to collect royalties on subsequent downstream products. Such agreements provide a way to value the patented research tool where valuation is uncertain.[24] The terms generally require royalties on the sales of downstream products that researchers identify or develop with a research tool and also can require an exclusive or nonexclusive license on future products or discoveries (*i.e.*, a grant back) or an option to acquire such a license.[25] In the biotech industry, for example, an owner of a patent on a receptor could enter into a reach-through licensing agreement with a pharmaceutical firm that would use the tool to learn more about the therapeutic effects of a potential product; however, the upstream patent owner would not earn royalties until the drug goes to market.[26]

26. Reach-through licensing agreements may create efficiencies if they allow risk–sharing between the parties.[27] These arrangements often provide for the waiver of any up-front fee to be collected by the upstream patent owner, and so can promote wider dissemination of the research tool to more biotech firms with limited investment capital.[28] Concerned that reach-through licensing agreements can also restrict access to upstream research tools when researchers must negotiate such licenses with multiple licensors in order to make new downstream products, the National Institutes of Health has adopted a policy restricting their use.[29]

27. DOJ and the FTC would apply "a rule of reason" analysis to evaluate these agreements, considering whether they would diminish competition in the properly defined market.[30] Factors bearing on this analysis include whether the agreement encourages unlawful coordination among competitors, inhibits market entry through exclusivity or exclusion, or reduces the incentive to innovate in the future.[31] Under a rule of reason analysis, the Agencies weigh these factors against the efficiencies of the particular arrangement.[32]

4.3 Patent Pools

28. Patent pools are often formed when multiple patent holders seek to simplify access to numerous patents that are necessary to make a product conforming to a standard or limited to a defined field of use. Patent pools are not subject to separate statutory or regulatory authority in the United States; instead, they are analysed under normal patent and competition laws. DOJ and the FTC discussed generally how they would analyse patent pools as part of their 1995 *Antitrust-IP Guidelines.*[33] Within the last few years the United States enforcement Agencies have analysed the competitive impact of several specific patent pools. DOJ has provided detailed specific guidance in its review of three proposed pools: the video compression technology proposal (MPEG-2); the three-company DVD proposal (3C DVD); and the six-company DVD proposal (6C DVD).[34] Although none of these matters involved biotechnology, the Agencies would expect to apply the same analysis in a biotech case. The FTC has provided guidance on patent pools through its 1998 challenge to a pool of patents related to lasers used in eye surgery to correct vision problems.[35] In addition, the United States Patent and Trademark Office has issued an official White Paper on patent pools, specifically in the area of biotechnology.[36] Each of these sources recognises that patent pools can have both procompetitive and anticompetitive effects.

4.3.A Pro- and Anticompetitive Effects of Patent Pools

29. There are several procompetitive justifications for patent pools. Patent pools can eliminate the problem of multiple blocking positions, defined as a situation where two or more patent holders can each block a product in the absence of a license from both. Patent pools may reduce transaction costs, since a licensee will find it more efficient to negotiate (or litigate) with a single pool licensor than with the pool's

36. *Clarifying Which Patents Are In the Pool*. Where a patent pool clearly explains which patents are within the pool, potential innovators can more easily design around the pooled patents in order to develop competing technologies.[45]

37. *Determining Whether the Antitrust "Safety Zone" Applies*. If the licensor and the licensees that are parties to a pooling arrangement collectively account for no more than 20 percent of each relevant market significantly affected by the pool, and the restraints associated with the pool are not facially anticompetitive, the federal antitrust enforcement agencies are not likely to challenge the pooling arrangement on antitrust grounds.[46]

NOTES

1. Many competition systems have design features that deliberately facilitate the evolution of doctrine in light of experience and advances in economic and legal learning. *See, e.g.*, William E. Kovacic & Carl Shapiro, *Antitrust Policy: A Century of Economic and Legal Thinking*, 14 J. Econ. PERSPECTIVES

(Address before the 2003 Mid-Winter Institute of the American Intellectual Property Law Association, Marco Island, Florida, Jan. 24, 2003), *available at* http://www.usdoj.gov/atr/public/speeches/200701.htm; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead* (Remarks before the Fall Forum of the American Bar Association Section of Antitrust Law, Washington, D.C., Nov. 15, 2001), *available at* http://www.ftc.gov/speeches/muris/intellectual.htm.

10. Other recent examples of joint DOJ and FTC work of this type include a joint workshop earlier this year on merger enforcement and an extensive set of hearings conducted in 2003 on competition policy and health care.

11. *See, e.g.*, Federal Trade Commission, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002) (presenting results of empirical study on entry of generic pharmaceutical products), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

12. This topic has been a theme of previous OECD contributions from the United States. *See, e.g.*, United States, *The Role of Research in the Design and Implementation of Competition Policy* 12 (Feb. 2004) (CCNM/GF/COMP/WD(2004)30)). *See also* William E. Kovacic, *Evaluating Antitrust Experiments: Using Ex-Post Assessments of Government Enforcement Decisions to Inform Competition Policy*, 9 GEO. MASON L. REV. 843 (2001) (examining importance to sound competition policy of ex post reviews of completed enforcement initiatives).

13. *See* William E. Kovacic, *Achieving Better Practices in the Design of Competition Policy Institutions* (Remarks before the Seoul Competition Forum 2004, Seoul, South Korea, Apr. 20, 2004) (discussing need for competition authorities to build networks to connect "archipelago" of government bodies that affect competition), *available at* http://www.ftc.gov/speeches/other/040420comppolicyinst.pdf.

14. *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert. denied*, 123 S.Ct. 2639 (2003) (describing the exception as "very narrow" and "strictly limited").

15. *Id.* at 1363.

16. *Id.* (remanding to the district court for consideration of these issues). Research institutions may also rely on another safe harbour for research activities that are undertaken solely for the purposes of developing

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Justice provides such guidance under the "Business Review Letter" process, codified at 28 C.F.R. § 50.6, which permits private parties to describe a business plan and receive a statement of the Antitrust Division's enforcement intentions.

35. *In re Summit Tech., Inc. and VISX, Inc.*, No. 9286 (FTC filed Mar. 24, 1998), *at* http://www.ftc.gov/os/1998/9803/summit.cmp.htm [hereinafter FTC *Summit-VISX* Complaint]; *In re Summit Tech., Inc. and VISX, Inc.*, No. 9286 (FTC Feb. 23, 1999), Decisions and Orders, *at* http://www.ftc.gov/os/1999/9903/d09286visx.do.htm (*VISX* Consent Decree), *at*