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DIRECTORATE FOR FINANCIAL, FISCAL AND ENTERPRISE AFFAIRS
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ROUNDTABLE ON INTELLECTUAL PROPERTY RIGHTS

-- Note by the US DOJ/FTC --

This note is submitted by the US DOJ/FTC to the Competition Committee FOR DISCUSSION at its forthcoming meeting (8-9 June 2004).

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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:

- recognise and account for interdependencies between the competition policy system and regimes governing the definition and exploitation of intellectual property rights;
- devise analytical approaches that account for the competitive benefits and hazards of complex commercial phenomena within the context of an unusually dynamic technology environment;[1] and
- build institutional capacity that is well-suited to diagnose the relevant commercial arrangements accurately and, where intervention is warranted, to take timely measures to correct competitive problems.

2. From either an analytical or institutional perspective, these tasks are among the most challenging that competition policy systems are called upon to address today.

3. Policymakers in the competition and intellectual property fields should adopt a more interdisciplinary orientation that focuses not only on competition policy or intellectual property policy in isolation, but also accounts for interrelationships between the two fields.[2] Competition policy agencies are likely to find that the economically sensible application of doctrine in the biotechnology sector and in industries featuring similar levels of innovation requires greater understanding of the intellectual property system and demands careful attention to each high technology sector's distinctive characteristics. Successful policy making in biotechnology and related areas may require adjustments in the operation of competition authorities, particularly in the form of resource allocation choices that entail greater investments in expanding their base of knowledge. In all of these areas, the focus of policymaking should not be limited to doctrinal concepts but also should address the effectiveness and capabilities of the institutions responsible for devising competition policy and intellectual property policy.[3]

1. Introduction

4. By letter of 24 March 2004, the Chair of the OECD Competition Committee invited delegates to contribute papers in preparation for the Roundtable on Competition Policy and Intellectual Property with a Focus on the Biotechnology Industry. The Chair's invitation solicited views about the interaction of the competition policy and patent policy systems and about specific competition issues that arise in the biotechnology field.

5. To a large degree, this paper summarises recent work of the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) on the interrelationship between competition policy and intellectual property policy. This contribution draws heavily upon the results of joint hearings that the DOJ and the FTC undertook in 2002 on the subject of Competition and Intellectual Property Law and Policy in the Knowledge Based Economy (Hearings).[4] Over the course of ten months, the DOJ and the FTC held 24 days of hearings and heard presentations from over 300 panellists, including representatives from academia, private industry, the private bar, and various government agencies. The FTC subsequently published a report, *To Promote Innovation*, that recommended adjustments in the patent system (FTC Innovation Report).[5] The DOJ and the FTC presently are completing a joint report addressing a range of issues concerning the design and application of antitrust doctrine to intellectual property.

6. The Hearings devoted special attention to the pharmaceutical, biotechnology, internet, and computer hardware and software industries. The proceedings indicated that both competition and patents play important roles in stimulating innovation in this field. The Hearings featured an active debate among participants, including disagreement about the degree to which the development of an "anticommons" was hindering innovation in biotechnology.[6] The results of the proceedings were generally consistent with the finding, reported below, that measures to ensure the robustness of the rights-granting process can make useful contributions toward discouraging the issuance of overbroad or weak biotechnology patents.

2. Recognising Interdependencies

7. The Hearings underscored the considerable degree of interdependency between the competition policy (CP) and intellectual property (IP) systems. Flaws in the regime through which a government grants IP rights can yield patents that are "questionable" or "weak" in the sense that a more robust process for vetting an application would have shown that the application failed to satisfy legal standards of patent-worthiness. When weak patents have true commercial significance,[7] such rights can curb competition and innovation unnecessarily. At the same time, faulty antitrust rules can diminish harmfully incentives to create and exploit IP rights.

8. A normative proposition that emerges from the recognition of CP-IP interdependency is the importance of efforts to address potential deficiencies within each regime. Inattentiveness to weaknesses in the rights-granting process may induce competition agencies or courts to apply antitrust doctrines expansively to mitigate the consequences of improvidently issued IP rights. In parallel fashion, the application of ill-conceived antitrust rules may lead courts to define IP rights broadly in an effort to eclipse the operation of the antitrust system. In either instance, the "first-best" solution is to correct flaws at their root rather than to rely on the "second-best" application of one body of legal doctrines to counteract the ill-effects of policies or rules generated in a separate area of law.

2.1 Patent Quality

9. Without reviewing all contributions from the Hearings or recounting the recommendations presented in the FTC Innovation Report concerning the U.S. patent system, it is possible to identify at least three basic measures that a regime for granting IP rights can take to achieve the innovation-related aims of patent policy without unnecessarily restricting competition.[8] Efforts to enhance the quality of the rights-granting process assume particular significance when the patent system in question creates strong presumptions of patent validity once a patent has issued.

10. *Adequate Resources*. One major determinant of patent quality is the level of resources provided to fund the operations of the rights-granting authority. The examination of patent applications involving biotechnology or other disciplines presenting similar technical complexity requires highly specialised

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. *Develop Lower Cost Mechanisms for Post-Grant Review of and Opposition to Patents*. An important ingredient of good patent system practice is the availability of a mechanism for post-grant review and opposition that permits meaningful challenges to patent validity. To date, global experimentation with various means of post-grant review has suggested interesting possibilities for using administrative processes, rather than the litigation of infringement claims in the courts, as relatively lower cost means to this end.

2.2 Competition Policy Doctrinal Quality

13. Competition policy institutions should strive to ensure that the design and application of competition doctrine does not unduly diminish incentives to create certain forms of intellectual property or impede the efficiency-enhancing arrangements for the exploitation of IP rights.[9] Ill-conceived antitrust rules not only impose social costs directly, but they also may induce courts to adopt doubtful interpretations of IP rights in an effort to blunt perceived overreaching by the antitrust system. Just as IP policymakers should be attentive to adverse spillovers associated with weaknesses in the rights-granting process, CP policymakers must consider the consequences of existing antitrust rules for the creation and exploitation of IP rights.

3. Institutional Implications for Competition Authorities

14. The issues and developments described above have a number of institutional implications for the operation of competition authorities. Presented below are approaches that competition agencies can take to improve the quality of policy involving areas, such as biotechnology, involving significant reliance on patents and substantial degrees of technological dynamism.

3.1 Increasing the Knowledge Base

15. One institutional implication of the foregoing discussion is the potential benefit to competition agencies from increasing their investments in activities that strengthen their base of knowledge. As noted below, such investments can take several forms.

16. *Hearings and Workshops*. The Hearings provided a valuable means for the U.S. competition agencies to compile a large body of information about the state of academic work at the CP/IP intersection and to collect the views of business officials about current industry developments. For CP/IP issues or for other subjects of competition policy, hearings and workshops can be useful instruments for informing competition agencies about noteworthy developments in theory and practice.[10]

17. *Empirical studies*. Empirical work about CP/IP issues can provide valuable insights for policymaking. Competition agencies can undertake such studies on their own[11] or regularly avail themselves of information gathering techniques, such as the hearings described above, to obtain the benefit of empirical work being done by other researchers.

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 multiple patent holders. Patent pools may also facilitate the integration of complementary technologies and help patent owners avoid costly infringement litigation.[37]

30. There also are several major risks of anticompetitive effects from patent pools. Patent pools can reduce competition if they include patents that otherwise would compete for licensees. The close cooperation necessary for a patent pool can similarly reduce competition by providing a forum for price fixing, collusion, and classic cartel behaviour. Patent pools also can foreclose innovation and entrench a dominant technology by discouraging research and development of new products and cost-reducing process innovations.[38]

4.3.B Factors for Analysis of Patent Pools

31. The United States applies a "rule of reason" analysis when examining the competitive impact of most licensing arrangements,[39] including patent pools.[40] Although no one factor is dispositive, competition authorities pay particular attention to the following issues when analysing the competitive effects of patent pools:

32. Limiting Pools to Complements; Avoiding Substitutes. Patent claims are "substitutes" if they involve products or processes that can compete with each other on a stand-alone basis. Patent claims are "complements" if they must be used concurrently, rather than alternatively, to achieve a particular product or process. Pooling of pure substitute technologies can decrease competition, whereas pooling of complementary patents can increase efficiency by removing the need to negotiate separate licenses for each product (among other factors).

33. *Safeguards Against Downstream Coordination*. Since a patent pool requires information sharing among its participants, the possibility exists that participants could coordinate to raise prices or fix other commercial terms. To lower this risk, patent pools should limit the collection of and access to competitively sensitive proprietary information of pool members and licensees.[41]

34. Nonexclusive, Non-discriminatory Licensing. To preserve a reward structure for the maximum number of potential innovations, patent pool licenses should be nonexclusive. This means not only that the pool license "out" to licensees should be nonexclusive, which permits the pool to work with as many end users as possible, but also that individual patent holders should license patents "into" the pool on a nonexclusive basis, thus preserving their ability to license individually outside the pool structure. Where pool participants retain the ability to license their patents outside the pool, a competitor can innovate around some patents in the pool and offer a different licensing package.[42]

35. Limiting the Scope of Grant backs. A "grant back" is a licensing term that requires the licensee to grant back to the licensor (and, in a pool, to the members of the pool) the right to use the licensee's existing and future patents.[43] Grant backs by patent pool licensees can ensure that no party can benefit from a pool while blocking others from using improvements to the standard specifications; however, if the terms of a grant back are too broad, they can deter follow-on innovation. To make grant backs more procompetitive, a pool might: (a) apply them only to innovations that rest upon existing pool patents; (b) limit them to complementary patents and not substitutes to the pool technology; and (c) make them nonexclusive, so licensees are free to license their own innovations to others.[44]

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 43 (Winter 2000) (describing the consciously evolutionary system embodied in the competition laws of the United States).

2. The distinction between intradisciplinary and interdisciplinary perspectives in treating competition policy and intellectual property policy is developed in William E. Kovacic & Andreas Reindl, *An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy* (Paper prepared for the Fordham Corporate Law Institute Program on Intellectual Property, New York, New York, Apr. 2004).

3. On the links between institutional arrangements and substantive competition policy outcomes, see Colin Scott, Institutional Competition and Coordination in the Process of Telecommunications Liberalisation, *in* International Regulatory Competition and Coordination 382 (Joseph McChahery *et al*. 1996) (analysing how different constitutional and institutional arrangements yielded contrasting telecommunications policy outcomes in the U.S. and EU, respectively); Gary Hewitt, "*Background Note*, 1 OECD J. COMPETITION L. & POL'Y 177 (1999) (reviewing ties between institutional regulatory design and substance of competition policy); William E. Kovacic, *Competition Policy in the Post consolidation Defense Industry*, ANTITRUST BULL. 421 (Summer 1999) (analysing how interaction of competition policy and public procurement institutions affects competition in procurement markets).

4. A complete index to these proceedings, along with links to hearing transcripts and submitted papers, can be found at http://www.ftc.gov/opp/intellect/index.htm.

5. FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) [hereinafter FTC Innovation Report], *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

6. The hearing proceedings involving the biotechnology sector are examined in Chapter 3, Section III, of the FTC's Innovation Report.

7. There is general understanding within the competition policy community that not all patents are commercially significant. For the most part, competition agencies and courts today generally foreswear the practice, reflected in earlier decisions and policy pronouncements, of calling patents "monopolies," as though the right to exclude inherent in the patent necessarily gave the holder of that right substantial market power. *See, e.g.*, U.S. Dep't of Justice & Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property § 2.2 (Apr. 6, 1995), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm [hereinafter *Antitrust-IP Guidelines*].

8. A central theme of the Hearings was the vital roles that both IP protection and competition can play in stimulating innovation.

9. *See, e.g.*, Makan Delrahim, *US and EU Approaches to the Antitrust Analysis of Intellectual Property Licensing: Observations from the Enforcement Perspective* (Remarks at the Spring Meeting of the American Bar Association Section of Antitrust Law, Washington, D.C., Apr 1, 2004), *available at* http://www.usdoj.gov/atr/public/speeches/203228.htm; R. Hewitt Pate, *Antitrust and Intellectual Property*

(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 and submitting required information to the Federal Food and Drug Administration. 35 U.S.C. § 271(e)(1) (2000), *Integra Lifesciences Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *reh'g en banc denied*, 2003 U.S. App. LEXIS 26547 (Fed. Cir. 2003) (limiting exception "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale, of drugs or veterinary biological products"). This safe harbour also applies to the development of medical devices toward that end, and includes experimental testing of generic copies of certain patented animal drugs and biological products. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669, 680 (1990); JUDICIARY COMM., GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT, H.R. REP. NO. 100-972(II) *at* 20 (Sept. 29, 1988), *reprinted in* 1988 U.S.C.C.A.N. 5659, 5673-74.

17. *See* FTC Innovation Report ch. 4, at 35-37 & n.228 (2003).

18. FTC Innovation Report ch. 4, at 35 & nn.222-223.

19. FTC Innovation Report ch. 4, at 34-37; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (May 1, 1998) [hereinafter Heller & Eisenberg, *The Anticommons*].

20. FTC Innovation Report ch. 4, at 36-37.

21. NATIONAL RESEARCH COUNSEL, A PATENT SYSTEM FOR THE 21ST CENTURY (2004) (prepublication copy).

22. *Id*. at 93-95.

23. *Id*. at 65-66 (citing *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627 (1999).

24. *See* Janice Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 16 (2001) [hereinafter Mueller, *Rethinking the Experimental Use Exception*].

25. Heller & Eisenberg, *The Anticommons* at 699. A grantback is a provision in a licensing agreement that allows the licensor the "to use the licensee's improvements to the licensed technology." *Antitrust-IP Guidelines* § 5.6.

26. Heller & Eisenberg, *The Anticommons* at 699.

27. *See id*.

28. *See* November 6, 2002 Hr'g Tr., "Relationships Among Competitors and Incentives to Compete: Cross-licensing of Patent Portfolios, Grantbacks, Reach-Through Royalties, and Non-Assertion Clauses" at 172 (Charles F. Rule), *available at* http://www.ftc.gov/opp/intellect/021106ftctrans.pdf [hereinafter Nov. 6 Tr.]; *see also* Mueller, *Rethinking the Experimental Use Exception* at 16.

29. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72090, 72091 (Dec. 23, 1999), *available at* http://ott.od.nih.gov/textonly/64FR72090.pdf; *see also* Nov. 6. Tr. at 152-53 (Barbara McGarey); Mueller, *Rethinking the Experimental Use Exception* at 8, 16 (discussing NIH's position).

30. *See Antitrust-IP Guidelines* § 3.1 (asking whether the a licensing restraint "harms competition among entities that would have been actual or potential competitors in a relevant market in the absence of the license.").

31. *See, e.g., Antitrust-IP Guidelines* §§ 3.1; *see also id.* § 3.2.3 (considering future innovation); *id.* § 4.1.2 (considering "licensing arrangements involving exclusivity"); *id.* § 5.5 (discussing portfolio cross licenses and patent pooling arrangements); *id*. § 5.6 (grantbacks).

32. *Cf. Antitrust-IP Guidelines* § 4.2 (considering "whether the restraint is reasonably necessary to achieve procompetitive efficiencies").

33. *Antitrust-IP Guidelines* § 5.5.

34. Letter from Joel I. Klein, Acting Assistant Attorney General, U.S. Dep't of Justice, to G[a]rrard R. Beeney, Esq. (June 26, 1997), *available at* http://www.usdoj.gov/atr/public/busreview/1170.pdf [hereinafter MPEG-2 Business Review Letter]; Letter from Joel I. Klein, Assistant Attorney General, U.S. Dep't of Justice, to Garrard R. Beeney, Esq. (Dec. 16, 1998), *available at* http://www.usdoj.gov/atr/public/busreview/2121.pdf [hereinafter 3C DVD Business Review Letter]; Letter from Joel I. Klein, Assistant Attorney General, U.S. Dep't of Justice, to Carey R. Ramos, Esq. (June 10, 1999), *available at* http://www.usdoj.gov/atr/public/busreview/2485.pdf [hereinafter 6C DVD Business Review Letter]. *See also* Letter from Charles A. James, Assistant Attorney General, U.S. Dep't of Justice, to Ky P. Ewing, Esq. (Nov. 12, 2002), *available at* http://www.usdoj.gov/atr/public/busreview/200455.pdf (review of licensing proposal for "third-generation" ("3G") wireless communication technologies). The Antitrust Division of the Department of

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* http://www.ftc.gov/os/1999/9903/d09286summit.do.htm (*Summit* Consent Decree).

36. Jeanne Clark *et al.*, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents*? (Dec. 2000), at 4-11, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

37. *Antitrust IP-Guidelines* § 5.5.

38. *See id.* For further discussion of the risk of anticompetitive effects, see the Department of Justice business review letters, *supra* note 34.

39. *Antitrust-IP Guidelines* § 4.

40. *See id.* §§ 4.1-4.3, 5.5.

41. 3C DVD Business Review Letter at 12; 6C DVD Business Review Letter at 12.

42. MPEG-2 Business Review Letter at 12-13; 6C DVD Business Review Letter at 12 n.66; *see* 3C DVD Business Review Letter at 12.

43. *Antitrust-IP Guidelines* § 5.6.

44. MPEG-2 Business Review Letter at 13-14; 3C DVD Business Review Letter at 12-13; 6C DVD Business Review Letter at 12-13.

45. *See, e.g.*, MPEG-2 Business Review Letter at 12.

46. *Antitrust-IP Guidelines* § 4.3. A pooling arrangement that falls within this "safety zone" generally should pass muster even if it involves features that otherwise typically might be problematic . Pooling arrangements cannot qualify, however, for safety zone treatment if they are used as vehicles to facilitate collusion.