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COMPETITION COMMITTEE**

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**ROUNDTABLE ON COMPETITION, PATENTS AND INNOVATION**

**-- Note by the US Department of Justice and the US Federal Trade Commission --**

*This note is jointly submitted by the US Department of Justice and the US Federal Trade Commission to the Competition Committee FOR DISCUSSION at its forthcoming meeting to be held on 18-19 October 2006.*

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## 1. Summary

1. Patent policy has been crucial to the high level of innovation in the United States, and innovation has been an important driver of increased consumer welfare. The state of innovation in the United States and developed countries is generally healthy, and patent policy is a part of a status quo that has benefited consumers; therefore, competition agencies should formulate antitrust policy concerning patents with care, and approach proposed changes to patent policy with caution. For a number of reasons, antitrust law is not an appropriate tool for correcting errors in the patent system; it should not be used simply to second-guess or limit the decisions of patent authorities. In particular, competition authorities should be careful that their actions do not undermine the predictability of patenting and patent enforcement.

2. At the same time, competition is also a driver of innovation, and competition agencies should continue to foster competition's ability to confer benefits in that role. The United States agrees that competition authorities have a significant role to play in promoting innovation. For example, they can participate in public debate concerning patent policy by providing expertise in economic analysis and insights into the role of competition in promoting innovation. Moreover, they can clarify antitrust rules governing agreements and collaborations involving IP in a manner that increases predictability and promotes innovation. The U.S. competition authorities have played both roles.

## 2. Introduction

3. This paper draws, in part, upon the recent work of the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) exploring the relationship between competition policy and intellectual property policy. During 2002, the DOJ and FTC held 24 days of hearings devoted to this topic and heard presentations from over 300 panellists, including representatives from academia, private industry, the private bar, and various government agencies. The FTC/DOJ Hearings devoted special attention to the pharmaceutical, biotechnology, Internet, and computer hardware and software industries. The FTC subsequently published a report entitled *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, which recommended adjustments in the patent system (FTC Report).<sup>1</sup>

4. This paper also reports on several recent patent law developments arising in the three branches of the U.S. government: the legislature, the courts, and the executive agencies. While many of these developments – particularly in the legislature – have not yet reached a conclusion, the recent activity suggests an increasing appreciation of economic principles in the formation of patent policy, including strategies to prevent economic harm from invalid or unenforceable patent claims. These developments potentially could result in significant changes to the U.S. patent system. In addition, this paper describes several instances where U.S. competition policy has successfully addressed challenges to innovation in a manner that encourages innovation.

## 3. The Relationship Between Patent and Competition Policy in Promoting Innovation

5. Patent policy and competition policy ultimately share the same goal: to strengthen economies and improve consumer welfare. While patent policy's focus on promoting innovation is perhaps more immediately obvious, innovation is no less important to competition policy: competition policy can be

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<sup>1</sup> Federal Trade Commission, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, (Oct. 2003) (hereinafter, "FTC Report"), available at <http://www.ftc.gov/opa/2003/10/ipreport.htm>.

understood in terms of promoting efficiency,<sup>2</sup> and innovation is key to “dynamic efficiency,” as many economists have suggested.

6. “Static efficiency” describes the tendency of firms in a competitive marketplace to reduce costs by refining existing products and capabilities. In a competitive economy, rival firms quickly adapt to an existing technology and drive the price of products and services embodying that technology down to something close to the cost of unit production (“marginal cost”). While this process is a significant force in improving consumer welfare, sometimes the greater driver of growth is “dynamic efficiency,” which refers to gains that result from entirely new ways of doing business. The economist Joseph Schumpeter described dynamic efficiency as “competition from the new commodity, the new technology, the new source of supply, the new organisation . . . competition which commands a decisive cost or quality advantage and which strikes not at the margins of the profits and the outputs of the existing firms but at their foundations and their very lives.”<sup>3</sup>

7. A potential problem for competition policy is that the same forces that yield the benefits of static efficiency – *e.g.*, conditions that encourage rivals quickly to adopt a new business method and drive their production toward marginal cost – may discourage innovations (and thus dynamic efficiency) if this drive toward marginal costs occurs at such an early stage that it makes innovation uneconomical. In industries where innovation requires substantial fixed investments or up-front research and development (R&D) costs, a rational firm may elect not to innovate if it anticipates a selling environment that quickly resolves to marginal cost.<sup>4</sup> When deciding upon uses of their available capital and effort, rational firms carefully weigh profit opportunities from innovation efforts against profit opportunities from other activity.

8. Seen in this light, patent protection should be viewed not as a concept separate from competition principles, but as a subset of competition policy. Properly applied, patent protection can create the space necessary to permit firms in a highly competitive market to profit from their inventions for limited times, which encourages innovation effort. Valid patents thus encourage firms to engage in competition through innovation by promoting innovative effort and dynamic efficiency. Patent policy, therefore, is clearly complementary to competition policy.

9. The FTC/DOJ Hearings, along with the FTC Report, confirmed that both competition and patents play important roles in stimulating innovation. The complementary nature of these two systems in encouraging innovation stretches across industries. Panellists at the Hearings reported that the degree to which innovation depended on one system or the other, however, varied somewhat by industry, as explained below.

### **3.1 Patents Promote Innovation**

10. Patent policy benefits the public by providing an incentive to develop and commercialise inventions with substantial utility. Without patent protection, innovators that produce intellectual property may not be able to appropriate sufficient benefits of their innovation to justify their creative effort, since intellectual property is particularly susceptible to misappropriation and free riding. The problem is especially acute when the original innovator’s efforts entail substantial fixed costs, and the imitators can

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<sup>2</sup> *E.g.*, Gerald F. Masoudi, *Intellectual Property and Competition: Four Principles for Encouraging Innovation*, address at the Digital Americas 2006 meeting (Sao Paulo, Brazil, April 2006) 13-15, *available at* <http://www.usdoj.gov/atr/public/speeches/215645.pdf>.

<sup>3</sup> JOSEPH SCHUMPETER, *CAPITALISM, SOCIALISM AND DEMOCRACY* 84 (Harper Perennial 1976) (1942).

<sup>4</sup> For example, Hearings participants in the pharmaceutical industry expressed concern about their ability to recoup their substantial R&D costs, and the importance of patents in achieving both recoupment and profits. FTC Report, Ch. 3 at 11-12.

copy the innovation cheaply. Patent rights mitigate this problem by granting exclusive rights in innovations, enhancing appropriability. The need for such protection has long been understood; the original articles of the U.S. Constitution, adopted in 1789, authorise Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries.”<sup>5</sup>

11. Patents can also facilitate commercialisation of the invention that the patent protects. Patent rights make it easier for inventors to develop relationships with others who invest in the further work needed to commercialise the invention. Moreover, the public disclosure of scientific and technical information is part of the consideration that the inventor gives the public, and such disclosure can stimulate further scientific progress.<sup>6</sup>

12. At the FTC/DOJ Hearings, representatives from the pharmaceutical industry stated that patent protection is indispensable in promoting pharmaceutical innovation for drug products. By preventing rival firms from free riding on the innovating firms’ discoveries, patents can enable pharmaceutical firms to cover their fixed costs and recoup their high levels of investment in R&D efforts.<sup>7</sup> Representatives from the biotechnology industry explained that many biotechnology companies conduct basic research to identify promising products, and then partner with a pharmaceutical company to test and commercialise the product. They seek patent protection to attract investment from capital markets, and to facilitate inter-firm relationships, such as licensing and joint ventures, necessary for commercial development of their inventions.<sup>8</sup>

### 3.2 *Competition Promotes Innovation*

13. The FTC Report found that competition can also stimulate innovation. Economic theory and empirical evidence suggest that the effect of an increase in competition on innovation will vary from one context to another. For example, panellists stated that firms in a competitive market generally have greater incentives to innovate than a monopolist that does not face the threat of entry.<sup>9</sup> In some industries, firms often innovate to exploit first-mover advantages (at least when, among other things, copying the innovation is expensive or time-consuming).<sup>10</sup> Moreover, some panellists noted that firms competing to innovate will approach research problems differently, increasing the chances of successful innovation.<sup>11</sup> Panellists also debated the hypothesis, originally espoused by Schumpeter, that “large and often monopolistic enterprises” are “the principal engines of technological progress.” Some critiqued this hypothesis directly, while others contended that the hypothesis is true for some industries but not in others.<sup>12</sup>

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<sup>5</sup> U.S. Const. Art. I, § 8. Other sections of this constitutional provision authorise copyright law.

<sup>6</sup> See FTC Report, Ch.2 at 3-7.

<sup>7</sup> FTC Report, Ch. 3 at 11-12.

<sup>8</sup> FTC Report, Ch. 3 at 15, 17-18.

<sup>9</sup> FTC Report, Ch. 3 at 9-10; see generally Kenneth J. Arrow, *Economic Welfare & the Allocation or Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY, 609, 619 (1962).

<sup>10</sup> FTC Report, Ch. 2 at 9-12.

<sup>11</sup> FTC Report, Ch. 3, at 15-16.

<sup>12</sup> FTC Report, Ch. 3 at 12-15; see generally SCHUMPETER, *supra* n. 3.

14. At the FTC/DOJ Hearings, many participants representing computer hardware companies observed that competition, rather than patent protection, drives innovation in their industries.<sup>13</sup> In the semiconductor industry, for instance, obtaining lead-time over rivals (a function of the competitive process) and trade secret protection provide the key mechanisms for appropriating returns on R&D investments.<sup>14</sup> Representatives of software and Internet companies made similar observations that competition to commercialise the most recent technological advance provides the primary driver of innovation.<sup>15</sup>

### 3.3 *Patent and Competition Policy Must be Balanced*

15. The FTC Report found that an appropriate balance between competition and patent policy will promote a greater degree of innovation. Errors or systematic biases in how one policy's rules are interpreted and applied can harm the other policy's effectiveness.

16. When a patent confers market power, it provides its owner with the ability to restrict production or charge prices that would be lower in the absence of a patent. To the extent that the promise of patent protection is necessary to stimulate invention, these static effects are necessary to promote dynamic efficiency. If the promise of patent protection is not necessary for those purposes, however, then the reduced output or higher prices are inefficient. For that reason, an important goal of the patent system is to provide a "means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent."<sup>16</sup>

17. The FTC Report found that patents that are invalid or have overly broad, unclear claims can impair competition, innovation and the economy. They present a significant concern because they can cause unwarranted market power, unjustifiably increase costs, and hamper competition that otherwise would stimulate innovation. For instance, such patents deter innovation if they lead the patentee's competitor to forgo R&D in areas that the patent improperly covers. Allowing patents on obvious inventions can thwart competition that might have developed based on the obvious technology. Expensive and time-consuming patent litigation to challenge a patent on an obvious technology wastes resources. If a competitor chooses instead to negotiate a license and pay royalties to avoid that costly and unpredictable litigation, the costs of follow-on innovation and commercial development increase due to the unjustified

<sup>13</sup> FTC Report, Ch. 3 at 31-32. See, e.g., *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Robert Barr Testimony, Feb. 28, 2002, at pages 673-74 (hereinafter, citations to transcripts of these hearings state the speaker's last name, the date of testimony, and relevant page(s)) ("[Cisco System's] growth was obviously not fuelled by patents, it was fuelled by competition and by open, non-proprietary interfaces."); Rhoden 2/28 at 754 ("[C]ompetition is what drives . . . innovation; patents have almost nothing to do with innovation."); Zanfagna 3/20 at 90 ("[I]nnovation is driven by competition in all of our markets."); Detkin 2/28 at 751 ("[T]he clear driving force behind innovation is competition.").

<sup>14</sup> FTC Report, Ch. 3 at 31 (citing W.M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)*, National Bureau of Econ. Research Working Paper No. 7552, 2000, available at <http://papersdev.nber.org/papers/27552>).

<sup>15</sup> FTC Report, Ch. 3 at 46. Kohn 2/27 at 350 ("[I]nnovation generally is promoted by competition."); see also, Chaikovsky 2/27 at 385; Friedman 2/27 at 354; Musacchia 4/9 at 44-45; Stallman 4/9 at 17-18. Competition also plays a key role in pharmaceutical innovation, in that the competition spurred by entry of a generic drug product (usually, after a pioneering patent expires) has forced brand-name firms to invent with new products to replenish their revenue streams. FTC Report, Ch. 3 at 11 (citing Glover 3/19 at 146).

<sup>16</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966).

royalties.<sup>17</sup> Moreover, such patents contribute to problems associated with “patent thickets,”<sup>18</sup> in which hundreds or even thousands of patents cover a single product. Firms spend resources obtaining “defensive patents,” not to protect their own innovation, but to have “bargaining chips” to obtain access to others’ patents through a cross-license or to counter allegations of infringement.<sup>19</sup>

18. Conversely, competition policy could undermine the innovation that the patent system promotes if overzealous antitrust enforcement were to restrict the procompetitive use of patent rights. Although the issues surrounding the proper application of antitrust law to intellectual property matters are vitally important to achieving a high level of innovation, this paper addresses them only briefly in deference to the questions presented in the request for papers. The DOJ and FTC will soon complete a joint report addressing these antitrust issues, based on the FTC/DOJ Hearings.

#### 4. Role of Competition Authorities in Promoting Reforms within the Patent System

19. Competition authorities may approach the relationship between patent and competition policy from at least two directions. Of course, they must formulate and apply antitrust policy to patent matters in a manner that appreciates the patent system’s incentives to innovate and addresses challenges to innovation, as discussed in Section 6 below. Additionally, they may promote reforms within the patent system that achieve a greater appreciation of economic and competition principles, as discussed in this section.

20. Competition authorities have a core competency in examining the effects of restraints, other conduct, and rules on consumer welfare, especially when this analysis is performed through empirical research and the use of economists. They have experience in an effects-based method of inquiry. They can play a meaningful role in advising patent policy makers on the impact of current laws on competition generally, and thus play a constructive role in promoting reforms within the patent system. To the extent that input from competition policy helps to improve the procompetitive effects, transparency, and predictability of the patent system itself, consumer welfare will benefit.<sup>20</sup>

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<sup>17</sup> Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. L. Rev. 1495, 1517 (2001) (noting that “patent owners might try to game the system by seeking to license even clearly bad patents for royalty payments small enough that licensees decide that it is not worth going to court”); *Id.* (royalties on improperly granted patents cause an inefficient allocation of society’s resources and a transfer that “encourages patenting and discourages competition to a greater extent than is socially optimal.”). An unjustified royalty may result in higher prices to consumers, inefficiently low use of the affected products, and deadweight loss. See Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in *Innovation Policy and the Economy* 119, 125 (Adam Jaffe et al. eds., 2001).

<sup>18</sup> A “patent thicket” is a “dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialise new technology.” Shapiro, *supra* note 17 at 120.

<sup>19</sup> The FTC heard extensive testimony related to all of these problems at the hearings underlying its IP Report. *Id.* Exec. Summ. at 1-7; Ch. 2 at 7-8; Ch. 3 at 20-26, 33-41, 50-55; Ch. 4 at 5; Ch.5 at 2-4. In April 2004, the National Academies of Science issued a report, *A Patent System for the 21<sup>st</sup> Century*, (the NAS Report), which echoed several of the FTC recommendations and noted its similarities to the FTC IP Report. The NAS Report is available at <http://www.nap.edu/html/patentsystem>. The NAS Report concluded that poor quality patents can hinder innovation for many of the reasons also discussed in the FTC’s IP Report. NAS Rpt. at 37-38, 95. It also recommended applying the obviousness standard more vigorously. *Id.* at 87-90.

<sup>20</sup> Deborah Platt Majoras, A Government Perspective on IP and Antitrust Law, address at the American Antitrust Institute (Washington, D.C., June 21, 2006) available at <http://www.ftc.gov/speeches/majoras/060621aai-ip.pdf>.

21. However, competition authorities must appreciate that changes to the patent system should be approached with caution. This principle is particularly important in light of the observation that the pace of innovation in developed economies in the second half of the twentieth century and currently has been robust, by any measure, and has been a key driver of global expansion and improved living standards. While it is impossible to determine precisely the effect of the patent system on this state of affairs, the patent system must be seen as a part of a generally successful status quo.

22. The FTC Report proposed reforms within the patent system, as explained below, and the U.S. antitrust agencies continue to play a role in policy and legislative debates within the patent system. Of particular note, the agencies frequently participate in the formulation of the government's *amicus curiae* (friend of the court) position briefs in Supreme Court cases involving intellectual property issues;<sup>21</sup> for example, they appeared on the United States' brief in *Illinois Tool Works Inc. v. Independent Ink, Inc.*,<sup>22</sup> together with counsel for the U.S. Patent and Trademark Office, and successfully argued in an antitrust "patent tying" case that the mere fact that a tying product is patented does not support a presumption of market power in that product.<sup>23</sup>

#### 4.1 *The FTC Report*

23. At the Hearings underlying the FTC Report, one issue stood out for the widespread agreement it generated among panellists: the importance of patent quality in maintaining a balance between patent and competition policy. Panellists extensively discussed patent quality and its fundamental determinants, such as the procedures through which patents are examined, re-examined, and litigated.<sup>24</sup> On that basis, the FTC Report made several recommendations aimed at improving patent quality, including:<sup>25</sup>

24. *Provide Adequate Funding for the PTO.* One major determinant of patent quality is the level of resources provided to fund the operations of the Patent and Trademark Office (PTO.) The examination of patent applications often requires highly specialised skills. Not only must the PTO recruit and retain skilled specialists, but the office also must afford examiners sufficient time to undertake a proper inquiry of the proposed invention and the prior art.

25. *Implement Robust Pre-Issuance Examination Procedures.* The Report recommended that the PTO establish procedures that allow examiners to request and obtain additional information from applicants concerning the prior art or the claimed invention. (The proposed PTO regulations described below generally fall into this category.)

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<sup>21</sup> *Id.*

<sup>22</sup> Brief for the United States as Amicus Curiae, *Illinois Tool Works Inc. v. Independent Ink, Inc.*, No 04-1329 (S. Ct.), 2005 WL 1864093 (Aug. 4, 2005).

<sup>23</sup> *See Illinois Tool Works Inc. v. Independent Ink, Inc.*, 126 S.Ct. 1281 (2006) (abrogating prior cases that were interpreted to require such a presumption).

<sup>24</sup> FTC Report, Ch. 3 at 20-21.

<sup>25</sup> *See, e.g.*, FTC Report, Executive Summary at 7-14. Beyond those recommendations aimed at improving patent quality, the FTC Report made other recommendations, which aimed, for instance to improve the disclosure function of the patent system. *See, e.g., id.*, Executive Summary at 16-17 (recommending changing the predicates for finding wilful infringement); *id.*, Executive Summary at 15-16 (recommending that all patent applications be published 18 months after filing).

26. *Create a New Administrative Procedure for Post-Grant Review of Patents.* The FTC Report found that existing means for challenging questionable patents are inadequate. Patent prosecution is *ex parte*, involving only the PTO and the patent applicant. Once a questionable patent has issued, the most effective way to challenge it is through litigation, but that path is extremely costly and lengthy, and normally is not an option unless the patent owner has threatened the potential challenger with patent infringement litigation. For these reasons, the FTC recommended institution of a meaningful post-grant review and opposition procedure.

27. *Tighten Legal Standards Used to Evaluate Whether a Patent is “Obvious.”* U.S. patent law precludes patenting if the differences between the claimed invention and the prior art are “obvious.” Patents on obvious technology “hav[e no] social benefit[,] because . . . others would have developed the idea even without the incentive of a patent.”<sup>26</sup> Because proper application of this statutory requirement is crucial to prevent the issuance of patents on trivial inventions that might unduly harm competition, the FTC Report recommends tightening certain legal standards used to evaluate whether a patent is obvious. One of those standards, the “suggestion test,” is the subject of the *KSR* case currently before the U.S. Supreme Court, as explained in section 5.1 below.

## 5. Recent Developments and Proposals for Changes to the Patent System in the U.S.

28. All three branches of the U.S. government – the judicial, the executive, and legislative – currently have under review cases or proposals for changes related to the patent system. Many of these proposals stem from the recognition that it is desirable to increase patent quality and to subject questionable patents to increased scrutiny. The U.S. Supreme Court recently granted review of two cases that offer the potential substantially to change the patent system: *KSR v. Teleflex* and *MedImmune v. Genentech*; and it has decided one: *eBay v. MercExchange*. The PTO has issued for public comment a series of proposed rules modifying the procedures for patent examination and review. Finally, both houses of the Congress are considering legislation implementing changes to the patent system.

### 5.1 Supreme Court Litigation

29. *KSR.* In June of this year, the Supreme Court granted *certiorari* (announced its decision to review) the case *KSR v. Teleflex*.<sup>27</sup> *KSR* presents the question of when a patent should be denied or invalidated on the grounds that the claimed invention is “obvious” to a hypothetical person of ordinary skill in the pertinent art, in light of the content of the prior art and the inventive skill attributable to such a person.<sup>28</sup> At issue is whether the Federal Circuit – the intermediate appellate court with jurisdiction over almost all patent appeals in the U.S. – improperly burdened the statutory analysis of obviousness by imposing its “suggestion” test. The suggestion test requires that a patent examiner seeking to reject a patent application, or a litigant seeking to invalidate a patent, make a specific demonstration of some “suggestion, teaching, or motivation” that would have led a person of ordinary skill in the art to combine the prior art to create the claimed invention.<sup>29</sup> As the *KSR* case illustrates, application of the “suggestion

<sup>26</sup> Merges & Duffy, PATENT LAW AND POLICY: CASES AND MATERIALS at 646.

<sup>27</sup> *KSR International Co. v. Teleflex, Inc. & Technology Holding Co.*, No. 04-1350 (S.Ct.).

<sup>28</sup> 35 U.S.C. § 103 (A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.); *Graham v. John Deere Co.*, 383 U.S. 17-18 (1966) (setting forth a methodology for analysing obviousness).

<sup>29</sup> See, e.g. *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1359-60 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (reversing PTO conclusion that patent was obvious after finding no



test” often presents the dispositive issue in assessing whether a patent is obvious. The Supreme Court invited the U.S. government’s view on whether to take the case, and in 2006 the government filed a brief urging review.<sup>30</sup>

30. The government’s brief reiterates that this case, and the questions that it raises concerning the proper standard for obviousness, has a substantial impact on commercial enterprise and innovation.<sup>31</sup> The FTC Report found that the economic consequences of patents that should be deemed obvious (and therefore invalid) can be significant, as explained in section 3.3 above. In line with these interests, the government’s brief argues that the “suggestion” test is too restrictive because it places undue emphasis on finding explicit statements that provide a suggestion to combine existing elements into the claimed invention, while leaving little room for the possibility that “persons of ordinary skill in the art” could combine elements to solve a problem on their own initiative.<sup>32</sup> The test ignores other possible reasons for obviousness, such as the possibility that the solution to the problem may have been too obvious to bother to write down.<sup>33</sup> As such, it can permit patents on trivial inventions.

31. *MedImmune*. Also this year, the Supreme Court granted *certiorari* in *MedImmune, Inc. v. Genentech*.<sup>34</sup> This case presents the question of whether a patent licensee in good standing may bring a declaratory judgment action challenging the validity and scope of the licensed patent. The rule currently prevailing in the lower courts effectively precludes these suits.<sup>35</sup> The government filed an *amicus* brief in support these challenges and the case will be heard in the fall.

32. The government’s brief argues that the court of appeals’ rule requiring a reasonable apprehension of suit to establish standing in a patent declaratory judgment case is an overly rigid interpretation of the U.S. Constitutional requirements.<sup>36</sup> Instead, the government urges the Court to apply the traditional flexible, fact-based approach of whether an “actual controversy” exists: that is, whether there is a substantial controversy, between parties with adverse interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Applying this test, the brief argues that a licensee need not breach the agreement in order to present a justiciable controversy concerning a patent’s validity and scope.<sup>37</sup>

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suggestion to combine references, even though the collective references contained all elements of the claims).

<sup>30</sup> Brief for the United States as Amicus Curiae Supporting Petitioner, *KSR International Co. v. Teleflex, Inc. & Technology Holding Co.*, No. 04-1350 (S. Ct. Aug. 22, 2006) (“KSR merits brief”); *see also* Brief for the United States as Amicus Curiae, *KSR International Co.*, No. 04-1350 (S. Ct. May 25, 2006), 2006 WL 1455388 (“KSR cert. brief”).

<sup>31</sup> *KSR merits brief* at 2, 25; *KSR cert. brief* at \*18-19.

<sup>32</sup> *KSR merits brief* at 10, 16-23; *KSR cert. brief* at \*9-10. Similarly, the FTC Report stressed the importance of ascribing “an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art.” FTC Report, Ch. 4 at 15.

<sup>33</sup> *KSR merits brief* at 19; *KSR cert. brief* at \*14.

<sup>34</sup> *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608 (S.Ct.).

<sup>35</sup> *See, e.g., Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 13767, cert. dismissed, 543 U.S. 941 (2004).

<sup>36</sup> Brief of the United States as Amicus Curiae Supporting Petitioner, *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608 (S.Ct. May 15, 2006), 2006 WL 1327303, \*14-19.

<sup>37</sup> *Id.* at \*11, 19-23.

33. As the government’s brief explains, given the harm that invalid patents can inflict on competition and consumers, there is a strong public interest in ensuring that invalid patents may be challenged to the full extent permitted by the Constitution. Licensees are typically the only entities with enough knowledge and economic incentive to challenge invalid patents, but they may be unwilling to risk breaching the license for fear of an injunction and the threat of treble damages (which can be awarded for “wilful” patent infringement). As the brief explains, a rigid rule that denies licensees standing to challenge patents, absent breach, encourages continued royalty payments for patents that otherwise might be held invalid, which may be economically inefficient.<sup>38</sup>

34. *eBay*. In *eBay, Inc. v. MercExchange LLC*,<sup>39</sup> the Supreme Court held patent holders seeking permanent injunctions against patent infringers are required to satisfy the traditional four-factor test applied by courts of equity granting injunctive relief. The four-factor test requires a plaintiff to show that (1) it suffered an irreparable injury; (2) money damages are inadequate to compensate for that injury; (3) the “balance of hardships” favours the plaintiff, meaning that the hardship caused to the plaintiff by denying an injunction is greater than the hardship caused to the defendant by granting one; and (4) the public interest would not be disserved by a permanent injunction.<sup>40</sup> The United States government filed an *amicus* brief arguing that a permanent injunction should not be an automatic remedy for patent infringement. Because the U.S. Patent Act requires that injunctions in patent cases be awarded “in accordance with the principles of equity,”<sup>41</sup> the brief advocated application of the four-factor equitable test, but also noted that an evaluation of the equities typically will support granting an injunction against a patent infringer.<sup>42</sup> The Court agreed.

35. eBay operates an Internet site providing online auctions, among other services. MercExchange owns a patent on a business method for creating an electronic market that facilitates sales between private entities. MercExchange sued eBay for patent infringement, and the trial court found the patent valid and infringed; the court, however, after applying the four-factor equitable test, denied MercExchange’s motion for a permanent injunction.<sup>43</sup> The U.S. Court of Appeals for the Federal Circuit reversed in a short opinion, applying its “general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.”<sup>44</sup> The Supreme Court then granted *certiorari* to consider this “general rule.”<sup>45</sup>

36. In a unanimous opinion, the Supreme Court acknowledged that the Patent Act provides patent holders with the right to exclude others from “making, using, . . . or selling” the patented invention.<sup>46</sup> The Court, however, rejected the argument that this right alone justifies an “automatic” permanent injunction in

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<sup>38</sup> *Id.* at \*23-26.

<sup>39</sup> *eBay, Inc v. MercExchange LLC*, 126 S.Ct. 1837 (2006).

<sup>40</sup> *Id.* at 1839.

<sup>41</sup> 35 U.S.C. § 283.

<sup>42</sup> Brief for the United States as Amicus Curiae Supporting Respondent, *eBay Inc. v. MercExchange, L.L.C.*, No. 05-130 (S Ct. March 10, 2006), 2006 WL 622120, \*22-23. The government’s brief also argued, however, that when a non-practicing entity is able to use the threat of an injunction as leverage to extract a greater royalty than the value of the invention would mandate because of the infringers sunk costs, a court might properly conclude that injunctive relief is inappropriate. *Id.* at \*2.

<sup>43</sup> *MercExchange, LLC v. eBay, Inc.*, 275 F. Supp.2d 695, 714-15 (E.D. Va. 2003).

<sup>44</sup> *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005).

<sup>45</sup> *eBay, Inc.*, 126 S.Ct. at 1839.

<sup>46</sup> *Id.* at 1840; 35 U.S.C. § 154(a)(1).

favour of patentees. In so doing, the Court criticised a long-standing practice in the lower courts to issue such injunctions against patent infringers as a matter of course.<sup>47</sup> The Court also criticised the ruling of the trial court, stating that traditional equitable principles would not support “broad classifications” denying injunctive relief merely because a patentee exhibited “willingness to license its patents,” or had a “lack of commercial activity in practicing the patents.”<sup>48</sup> The Court then vacated and remanded the case for a more thorough consideration of an injunction under the four-factor test. The full Court provided no further guidance as to when an injunction is appropriate following a finding of patent infringement.

37. Seven of the nine justices, however, joined separate concurring opinions to discuss the matter further. While these concurrences do not have the force of law, they suggest areas for possible development by subsequent cases in the Supreme Court and lower courts.

38. A three-Justice concurrence, written by the Chief Justice, emphasised that while the Court’s decision reaffirmed the four-factor test and with it a trial court’s discretion to deny injunctions, there is a “long tradition” of courts granting injunctive relief upon a finding of infringement in the vast majority of patent cases.<sup>49</sup> These Justices emphasised that when applying the four factors, “a page of history is worth a volume of logic,”<sup>50</sup> which, in the context of the opinion, could be read as a caution to lower courts against frequent denials of permanent injunctions.

39. A four-Justice concurrence employed a slightly different emphasis, suggesting that competitive considerations may bear upon whether to grant an injunction. Referring to the FTC Report, these Justices noted that an industry has developed in which non-practicing entities (entities that do not commercialise products other than technology licenses) use patents not as a basis for producing goods but for obtaining license fees.<sup>51</sup> The Justices noted that for these firms, an injunction can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. The Justices stated that “when the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.”<sup>52</sup>

## 5.2 *Administrative Activity by the Patent and Trademark Office*

40. During 2006, the Patent and Trademark Office (PTO) published four sets of proposed regulations and procedures intended to improve the quality and efficiency of the patent examination process in the U.S., and to promote innovation and economic growth. These new regulations and procedures in some cases would increase the quality of information that patent applicants are required to provide to patent examiners, and, in others, seek to focus applicants on initially presenting their best claims and arguments. These proposed changes are as follows:

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<sup>47</sup> *eBay, Inc.*, 126 S.Ct. at 1839.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* at 1841-42 (Roberts, C.J., and Scalia, J. and Ginsberg, J., concurring).

<sup>50</sup> *Id.* at 1842.

<sup>51</sup> *Id.* at 1842 (Kennedy, J., Stevens, J., Souter, J., and Breyer, J., concurring).

<sup>52</sup> *Id.*

41. *Requesting More Timely and Useful “Information Disclosure Statements.”* The proposed rule requires patent applicants under certain circumstances to identify the most relevant information in the prior art related to their inventions in the early stages of the patent examination.<sup>53</sup>

42. *Offering Accelerated Examination in Exchange for More Focused Applications.* The proposed procedure allows applicants to file a request to receive within 12 months a final decision by an examiner on whether their applications for patents will be denied or granted. In exchange, the applicants must provide and explain the prior art, and state in specific ways why the claimed inventions are patentable.<sup>54</sup>

43. *Focusing Initial Patent Examination on Representative Claims.* The regulation would limit initial examination to ten representative patent claims. If more than ten representative claims are to be examined, the applicants would be required, among other things, to describe the prior art, and to state in specific ways why the claimed inventions are patentable.<sup>55</sup>

44. *Limiting Repetitive Continuation Applications.* Continued examination allows applicants to obtain further examination of a patent application after a “final rejection” by the examiner. These procedures sometimes lead to an unlimited string of filings with diminishingly useful communications between the patent examiner and the applicant. The proposed regulations limit proceedings in the PTO by requiring applicants, after they have received two full rounds of examiner review, to show why any new continuation submissions could not have been made previously.<sup>56</sup>

### 5.3 *Legislative Activity*

45. Three bills have been introduced in the United States House of Representatives and the United State Senate in the past two years proposing far-reaching reforms to the patent system.<sup>57</sup> Some provisions of the legislation incorporate aspects of recommendations made by the FTC Report. While the bills differ in scope and in the details of their implementation, they share several features. Among other things, the bills would establish a post-grant opposition procedure; change the standards for wilful infringement; and permit third parties to submit prior art during patent examination.<sup>58</sup>

46. *Post-Grant Patent Review.* All three bills create an expanded post-grant opposition procedure with many of the features the FTC Report recommended. The bills allow the public to dispute all issues of

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<sup>53</sup> Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (10 July 2006).

<sup>54</sup> Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination, 71 Fed. Reg. 36323, 36323-24 (26 June 2006).

<sup>55</sup> Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61 (Jan. 3, 2006).

<sup>56</sup> Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 48-49 (Jan. 2, 2006).

<sup>57</sup> Representative Lamar Smith, Chairman of the House Subcommittee on Courts, the Internet and Intellectual Property, introduced legislation entitled the “Patent Reform Act of 2005,” on June 8, 2005. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). Later that term, Representative Howard Berman, Ranking Member of the House Judiciary Subcommittee on Courts, the Internet and Intellectual Property, introduced legislation entitled the “Patents Depend on Quality Act.” H.R. 5096, 109th Cong. (2006). Finally, on August 3, 2006, Senators Orrin Hatch and Patrick Leahy, chairmen of the U.S. Senate’s intellectual-property panel, introduced a Senate bill on patent reform.<sup>57</sup> Patent Reform Act of 2006, S3818, 110th Cong. (2006).

<sup>58</sup> Each bill also contains other provisions not discussed here.

patentability before a board of administrative judges within the PTO based on limited discovery. Either party wishing to oppose the decision retains full rights of appeal.

47. *Limiting Wilful Infringement.* The three bills also establish new predicates for wilful infringement. Specifically, they limit findings of wilful infringement to those circumstances in which (i) the infringer continued to infringe after receiving specific written notice of infringement, (ii) the infringer intentionally copied the infringing device or process, or (iii) after having been found by a court to have infringed the patent, the infringer engaged in conduct that was not colorably different from the conduct previously found to have infringed the patent.

48. *Third Party Submission of Prior Art.* The bills permit third parties to submit prior art to the PTO during patent examination. They typically provide that the party that submits the reference must explain the relevance of the reference and pay a fee to defray PTO expenses and discourage frivolous submissions. This provision is intended to improve the quality of patents by giving examiners greater access to prior art when deciding patentability.

49. At this stage, it is too early to know which legislative proposals, if any, will be implemented. Debate and additional bills are likely to follow, and it is thus too early to predict the effects of the legislation on innovation.

## **6. Considerations when Formulating Antitrust Policy Involving Patent and Innovation Issues**

50. In economies increasingly based on high technology, competition authorities must frequently formulate and apply antitrust policy to matters involving patent and innovation issues. It is important that they do so in a manner that remains sensitive to the patent system's incentives to innovate and recognises challenges to innovation in order to give full weight to the dynamic efficiencies that have great potential to increase consumer welfare.

51. Firms making investment decisions seek clear, predictable rules as to how the patent and competition regimes will function together. Uncertainty can deter investment. Senior officials of the U.S. Department of Justice have observed that the search for the perfect can be the enemy of the good, and that while competition experts may find the most intricate balancing tests to be the most interesting, "[b]usiness does not run this way."<sup>59</sup> To the extent that competition enforcement is seen as a way to second-guess or address flaws within the patent system, it likely will create undesirable uncertainty. For that reason and others, antitrust law is not an appropriate tool for correcting errors in the patent system.

52. When formulating antitrust policy, competition authorities operate on firmest ground when they react to particular challenges within the patent system where anticompetitive effects are clear and solutions are administrable. This Section discusses examples of instances when competition policy has successfully addressed challenges to innovation in a manner that promotes innovation, such as the business reviews of patent pooling arrangements and passage of the Standards Development Organisation Advancement Act, and agency analysis of recent mergers. This Section also discusses a current effort regarding *ex ante* discussions of licensing terms within standards development organisations.

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<sup>59</sup> See Masoudi, *supra* n. 2, at 3.

## 6.1 Patent Pool Business Review Letters

53. The U.S. antitrust agencies analysed patent pools generally as part of their 1995 *Antitrust-IP Guidelines*.<sup>60</sup> The Department of Justice provided more 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).<sup>61</sup> Together, these letters established a predictable method for creating patent pools that are unlikely to be challenged as anticompetitive under U.S. antitrust laws.

54. Patent pools have a number of procompetitive justifications. They 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); reduce transaction costs, since a licensee will find it more efficient to negotiate with a single pool licensor than with the pool's multiple patent holders; distribute risks by increasing the chances that an innovator will receive at least some compensation for its invention, if it can persuade other patent holders to include the new patent in the pool; and provide an efficient mechanism for sharing useful non-patented information such as manufacturing secrets and medical dosing. Such pools also carry risks of anticompetitive effects, including the potential to exclude or inadequately compensate new innovation, thereby entrenching a dominant technology; reduce competition by combining patents that otherwise would compete for licensees; reduce a potential licensee's incentives to challenge invalid patents; or provide a forum for price fixing, collusion, and classic cartel behaviour.

55. The patent pool business review letters together provided a list of factors, not necessarily exclusive or required in every case, that could lessen the chances of anticompetitive effects and therefore challenge under antitrust laws. These included, among others: limiting pools to complements, and avoiding substitutes; using nonexclusive, non-discriminatory licensing; imposing safeguards against downstream coordination; limiting the scope of mandatory grant backs; and clarifying which patents are in the pool. Patent pooling has flourished under these guidelines in recent years and, with the exception of one case in which the FTC found a two-patentee pooling arrangement to be essentially a cover for price fixing regarding substitute patents,<sup>62</sup> the U.S. antitrust agencies have not found it necessary to litigate against patent pools. Pools have developed as a procompetitive way to deal with patent thickets, and competition policy has encouraged that development.

<sup>60</sup> U.S. Dep't of Justice & Federal Trade Comm'n, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (Apr. 6, 1995), at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>.

<sup>61</sup> Letter from Joel I. Klein, Acting Assistant Attorney General, U.S. Dep't of Justice, to G[ar]rard R. Beeney, Esq. (June 26, 1997), at <http://www.usdoj.gov/atr/public/busreview/1170.wpd> (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), at <http://www.usdoj.gov/atr/public/busreview/2121.wpd> (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), at <http://www.usdoj.gov/atr/public/busreview/2485.pdf> (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), at <http://www.usdoj.gov/atr/public/busreview/200455.pdf> regarding "third-generation" ("3G") wireless communication technologies.

<sup>62</sup> Complaint, *In re Summit Tech., Inc. and VISX, Inc.*, No. 9286 (FTC filed Mar. 24, 1998), available at <http://www.ftc.gov/os/1998/03/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, available at <http://www.ftc.gov/os/1999/03/d09286visx.do.htm>.

## 6.2 *Limited Safe Harbour for Standards Development Organisations*

56. The development of technology interoperability standards, when conducted in a procompetitive fashion, has been a significant factor in the growth of technology markets. Joint standard setting can reduce inefficiencies caused by incompatible devices, encourage combined best-of-breed solutions rather than solutions tied to only the technology of a single firm, and help participants to clear patent thickets.<sup>63</sup>

57. Standards development organisations (SDOs) often involve collaborations among competitors. While standards development is generally procompetitive, the potential for anticompetitive collaboration within SDOs exists. In recent years, the SDOs themselves – which are usually run as volunteer or non-profit enterprises – have expressed concern that their employees could be sued for treble damages under U.S. antitrust law, and that the threat of such liability could hamper procompetitive standards development efforts by reducing the willingness of talented people to run SDOs.

58. The U.S. antitrust agencies believe that the fear of significant liability for SDOs themselves (as opposed to members who might conspire) is largely unfounded; nevertheless, they acknowledge that competition could be harmed if qualified personnel refuse to staff SDOs due to fear of liability. The agencies worked with SDOs and the Congress to narrowly tailor a law to address this fear, while keeping intact the possibility of antitrust liability for SDO members who use standard setting as a cover for anticompetitive conduct. On June 22, 2004, the President signed into law the Standards Development Organisation Advancement Act.<sup>64</sup> The Act grants SDOs (although not standard setting participants) limited immunity from treble damages in antitrust actions on the condition that the SDOs file proper notification of their activities with the agencies.<sup>65</sup> The agencies later issued guidance on the filing requirements, stating, among other things, that SDOs should file documents showing the nature and scope of the standards development activity.<sup>66</sup> SDOs have taken advantage of this program in large numbers and appear to believe that the Act has allayed their fears.

## 6.3 *Ex Ante Licensing Negotiations in SDOs*

59. Standards development organisations typically require that their members agree to license any technology contributed to the standard on a “reasonable and non-discriminatory” (RAND) basis. Problems sometime arise when a standard effectively creates market power for a patentee, and the patentee and its licensees disagree over what price would be reasonable. A solution to this type of *ex post* negotiation, which is prone to patent hold-up, is *ex ante* negotiation. However, SDOs and their members have been reluctant to engage in *ex ante* discussions of technology licensing structures and rates, in part due to a fear of antitrust liability under a monopsony theory: theoretically, a plaintiff could claim that by engaging in *ex ante* negotiations, potential licensees would drive technology fees below competitive levels and thereby damage innovation incentives.

60. The U.S. antitrust agencies have clarified their policies toward *ex ante* licensing through a series of public statements. Hewitt Pate, former Assistant Attorney General for Antitrust, addressed this issue in 2005 and concluded that a rule of reason analysis was appropriate, balancing the monopsony concern

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<sup>63</sup> FTC Report, Ch. 3 at 43.

<sup>64</sup> P.L. 108-237 (June 22, 2004), codified as amendments to 15 U.S.C. §§ 4301-05.

<sup>65</sup> 15 U.S.C. § 4303 (as amended).

<sup>66</sup> Federal Trade Commission, Notice on Implementation of the Standards Development Organisation Advancement Act of 2004 (June 24, 2004), [www.ftc.gov/opa/2004/06/sdoaa.htm](http://www.ftc.gov/opa/2004/06/sdoaa.htm).

against the inefficiencies of *ex post* negotiations and licensing hold up.<sup>67</sup> He noted that “[i]t would be a strange result if antitrust policy is being used to prevent price competition.”<sup>68</sup> More recently, in an address devoted to the subject, FTC Chairman Majoras stated that “joint *ex ante* royalty discussions that are reasonably necessary to avoid hold up do not warrant *per se* condemnation. Rather, they merit the balancing undertaken in a rule of reason review.”<sup>69</sup>

61. The threat of monopsony effects from *ex ante* SDO licensing negotiations, while possible, is unlikely to be a frequent practical concern. Factors such as SDO members’ pre-standard lack of buying power, SDO members’ status as potential licensors, and the possibility that low rates will reduce the widespread participation necessary for an SDO effort, should temper the ability or desire to drive royalty rates below competitive levels.<sup>70</sup> The agencies have expressed their willingness to issue business reviews on appropriate SDO plans in this regard.

#### 6.4 Mergers

62. The U.S. antitrust agencies also attempt to promote innovation through competition policy in the merger review process. Many of the mergers that the agencies review reflect the increased importance of intellectual property in twenty-first century markets. In evaluating mergers in technology-intensive or R&D-intensive industries, the agencies apply their joint 1992 Horizontal Merger Guidelines, as they do in more traditional industries. These Guidelines specifically recognise that a reduction in innovation is one of the ways in which a seller with market power may lessen competition.<sup>71</sup> While merger analysis is by its nature forward-looking and predictive, the agencies avoid undue speculation regarding the likely ways in which technology ultimately will be developed and marketed, given the unpredictability of research and the speed at which new development potentially can shift dynamic markets.

63. Two recent matters provide examples of how merger analysis can respond to concerns about innovation. First, the FTC in 2004 decided by a divided vote to close its investigation of the consummated merger of Genzyme Corp. and Novazyme Corp., the only two companies developing therapies for a rare disorder known as Pompe disease.<sup>72</sup> The FTC’s investigation focused on the transaction’s potential impact on the pace and scope of research into the development of a treatment for Pompe disease.

64. In his statement, then-Chairman Muris explained his conclusion that, based on the facts of the case, the transaction did not appear likely to reduce the incentives of the merged firm to invest in

<sup>67</sup> R. Hewitt Pate, Competition and Intellectual Property in the US: Licensing Freedom and the Limits of Antitrust, address at the EU Competition Workshop (June 3, 2005) 9-10, <http://www.usdoj.gov/atr/public/speeches/209359.pdf>.

<sup>68</sup> *Id.* at 9.

<sup>69</sup> Deborah Platt Majoras, Recognising the Procompetitive Potential of Royalty Discussions in Standard Setting, address at the forum on Standardisation and the Law (Stanford University, Sept. 23, 2005) 7, available at <http://www.ftc.gov/speeches/majoras/050923stanford.pdf>.

<sup>70</sup> *Id.* at 9.

<sup>71</sup> United States Dep’t of Justice and Federal Trade Commission, Horizontal Merger Guidelines (Apr. 2, 1992), reprinted in 4 Trade Reg. Rep (CCH) ¶ 13,104 at § 0.1, n. 6.

<sup>72</sup> File No. 021 0026, Closing of Investigation of Genzyme Corporation Acquisition of Novazyme Pharmaceuticals, Inc. (Jan. 14, 2004), available at <http://www.ftc.gov/opa/2004/01/genzyme.htm>. The Commission vote to close the investigation and to issue separate public statements was 3-1-1, with Commissioner Mozelle W. Thompson dissenting and Commissioner Pamela Jones Harbour not participating. Chairman Muris and Commissioner Harbour each filed separate written Statements, and Commissioner Thompson filed a dissent.



successful research and development, and that the transaction was more likely to produce efficiencies that could accelerate development of a life-saving treatment.<sup>73</sup> He determined that competition between the two entities would not have had a substantial effect on the amount or timing of either of their R&D spending on Pompe, or on when either of their therapies would reach the market.<sup>74</sup> Among other factors, then-Chairman Muris found it significant that during the two years since the merger had been consummated, Genzyme had not slowed its Pompe program.<sup>75</sup>

65. In another recent transaction, the FTC required a licensing remedy to preserve ongoing development of new drug therapies. In 2002, the FTC reviewed the merger of Amgen and Immunex. At issue were two markets for drugs used primarily to treat rheumatoid arthritis, as well as research and development into related new drug therapies. In both markets, the merger joined the dominant or only firm in the market with one of a very small number of serious would-be entrants. In each market, the consent order restored competition lost to the merger by requiring the merged firm to license key patents to a third party that had a product in clinical trials but that was allegedly blocked by the patents from entering. The license assured the third party that it had the freedom of operation necessary to market its competing product, and it allowed the merged firm to retain the rights needed to pursue development of its own competing products and new therapies.<sup>76</sup>

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<sup>73</sup> Statement of Chairman Timothy J. Muris in the matter of Genzyme Corporation / Novazyme Pharmaceuticals, Inc. (Jan. 14, 2004), *available at* <http://www.ftc.gov/os/2004/01/murisgenzymestmt.pdf>.

<sup>74</sup> *Id.* at 12-15.

<sup>75</sup> *Id.* at 14-17.

<sup>76</sup> In re Amgen/Immunex, FTC Docket No. C-4053, Analysis to Aid Public Comment at 2-3, *available at* [www.ftc.gov/os/caselist/c40561.htm](http://www.ftc.gov/os/caselist/c40561.htm); Complaint, at 5-6, *available at* <http://www.ftc.gov/os/caselist/c4056.htm>.