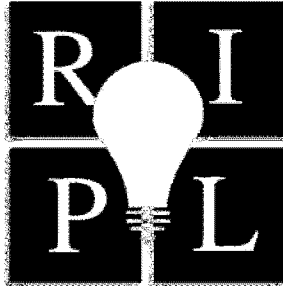


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



SUPPRESSION OF INNOVATION OR COLLABORATIVE EFFICIENCIES?: AN  
ANTITRUST ANALYSIS OF A RESEARCH & DEVELOPMENT COLLABORATION  
THAT LED TO THE SHELVING OF A PROMISING DRUG

SAAMI ZAIN

ABSTRACT

This article discusses antitrust issues present in research and development collaborations between competitors. In particular, it illustrates that, although often very beneficial, these collaborations may have the potential for considerable harm via suppression of innovation. The article examines a recent case involving a collaboration to develop drugs, which arguably resulted in the suppression of a promising drug.

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SUPPRESSION OF INNOVATION OR COLLABORATIVE EFFICIENCIES?: AN  
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THAT LED TO THE SHELVING OF A PROMISING DRUG

SAAMI ZAIN\*

INTRODUCTION

In 1998, a symposium was convened to discuss a particular issue in the much debated “conflict” or “tension” between intellectual property and antitrust: the suppression of technology.<sup>1</sup> Defining “suppression of technology” as “any type of conduct or agreement that limits the availability, use, or development of a particular process or product, or that limits or chills the ability of others to create or exploit such an innovative process or product,”<sup>2</sup> the participants evaluated the implications of technology suppression from an antitrust perspective. This article seeks to add to that discourse by examining a particular area which I believe has considerable potential for suppression: research and development (“R&D”) collaborations. However, this article proceeds not by an extensive analysis of law, economics, or policy, but by providing and evaluating an actual example where suppression occurred. Specifically, this article discusses and analyzes antitrust concerns raised by a collaboration of three firms for the development and commercialization of anti-IgE antibodies.<sup>3</sup> The article focuses on the firms’ ten year dispute over rights to develop these antibodies, which resulted in the abandonment of a drug which had promising results in clinical trials for the treatment of peanut allergies.<sup>4</sup> The drug was abandoned because two of the firms in the collaboration refused to allow the third firm to independently develop the drug, fearing that the drug would compete with a new drug developed by the collaboration—a drug developed for treating asthma.<sup>5</sup> The case is exceptional not only because the collaboration’s actions resulted in less potential competition and the abandonment of a promising drug, but also because it involves several notable issues in the patent-antitrust intersection. Part I of this article lays out the relevant facts of the case. Part II provides a brief introduction to antitrust law, focusing on those issues most pertinent to the facts. Part III examines the primary antitrust issues raised by the collaboration. Finally, Part IV concludes with my belief that competitive concerns raised by the

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\* Member, State Bar of California, New York; Candidate for Master of Laws, Trade Regulation (Antitrust), New York University, May 2006. I would like to thank David Hamilton of the *Wall Street Journal* for bringing this case to my attention. See David Hamilton, *Silent Treatment: How Genentech, Novartis Stifled a Promising Drug*, WALL ST. J., Apr. 5, 2005, at A1.

<sup>1</sup> All articles submitted in the symposium were subsequently published in Volume 66 of the *Antitrust Law Journal*, beginning at page 421. Joel M. Cohen & Arthur J. Burke, *An Overview of the Antitrust Analysis of Suppression of Technology*, 66 ANTITRUST L.J. 421, 424 (1998).

<sup>2</sup> *Id.*

<sup>3</sup> The collaboration occurred between Tanox, Novartis, and Genentech. See Hamilton, *supra* note \*, at A1.

<sup>4</sup> See Hamilton, *supra* note \*, at A1.

<sup>5</sup> See Hamilton, *supra* note \*, at A1.

collaboration are sufficiently troubling to warrant presumptive condemnation under antitrust law.

For the purpose of accuracy, and in fairness to the firms involved in the collaboration examined herein, a few brief disclaimers should be made. First, all the “facts” provided below were taken from public documents and primarily from court records in one particular case involving the collaborators.<sup>6</sup> As a result, the asserted facts amount to my interpretation of all purported facts, statements, assertions, and documents included in the public record.<sup>7</sup> Second, for the sake of simplicity, brevity, and relevance, this article only discusses events which involve antitrust issues. Consequently, certain facts are oversimplified or even omitted.

## I. FACTUAL HISTORY

Novartis and Genentech are large pharmaceutical companies that, among other activities, develop and commercialize drugs.<sup>8</sup> Genentech is based in San Francisco, CA, while Novartis is based in Basel, Switzerland.<sup>9</sup> Tanox is a Houston, TX biotechnology company specializing in the discovery and development of biotherapeutics based on monoclonal antibody technology.<sup>10</sup> Created in 1986, Tanox is a relatively small company whose first and only commercialized drug (as of December 2005) is XOLAIR, which was developed in collaboration with Genentech and Novartis. XOLAIR was approved by the U.S. Food & Drug Administration (“FDA”) in 2003 for the treatment of asthma in adults and adolescents.<sup>11</sup>

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<sup>6</sup> Other notable sources of public information include the companies’ own websites and annual reports submitted by the companies to the Securities & Exchange Commission (“SEC”).

<sup>7</sup> I viewed all public filings including pleadings, orders, and decisions in the case at the court house in San Francisco, CA on two consecutive days in June 2005. Despite taking notes and copying over 350 pages of the most pertinent documents, I cannot attest to the complete accuracy of all facts. Moreover, several of the documents and pleadings provided by Genentech and Novartis were redacted, while others were sealed.

<sup>8</sup> Novartis—A World Leader in Pharmaceuticals, [http://www.novartis.com/about\\_novartis/en/index.shtml](http://www.novartis.com/about_novartis/en/index.shtml) (last visited Apr. 23, 2006); Genentech—A Biotech Research and Information Company, <http://www.gene.com/gene/about/index.jsp?ei=utf-8&fr=slv1-&p=genentech> (last visited Apr. 23, 2006).

<sup>9</sup> Genentech: About Us—Our Locations, <http://www.gene.com/gene/about/locations/index.jsp?ei=utf-8&fr=slv1-&p=genentech> (indicating where the corporate headquarters are for Genentech) (last visited Apr. 23, 2006); Introduction History—Novartis.com, [http://www.novartis.com/about\\_novartis/en/history.shtml](http://www.novartis.com/about_novartis/en/history.shtml) (indicating where the headquarters are for Novartis) (last visited Apr. 23, 2006). Novartis was formed in late 1996 as a result of a merger between Ciba-Geigy and Sandoz. Joint Statement of Undisputed Facts ¶ 2, *Genentech, Inc. v. Tanox, Inc.*, No. 99-2060 (N.D. Cal. Mar. 14, 2001). Novartis is the successor-in-interest to all of Ciba’s pharmaceutical business including all of Ciba’s rights and obligations under the agreements discussed in this article. *Id.* Accordingly, for purposes of simplicity, I will refer to Novartis instead of Ciba-Geigy even when referring to actions and events occurring prior to the merger.

<sup>10</sup> Tanox—Home, <http://www.tanox.com/home/home.asp> (last visited Apr. 23, 2006).

<sup>11</sup> Tanox, Inc., Annual Report (Form 10-K), at 3 (Mar. 10, 2005), available at <http://phx.corporate-ir.net/phoenix.zhtml?c=120940&p=irol-sec> [hereinafter Annual Report]; see also Tanox—XOLAIR, <http://www.tanox.com/products/xolair.asp> (last visited Mar. 24, 2006).

In the 1980s, Tanox developed certain anti-Immunoglobulin E (“anti-IgE”) monoclonal antibodies for which it filed a patent.<sup>12</sup> Anti-IgE antibodies are genetically engineered antibodies that target specific antigens in the body for the treatment of immune-mediated diseases, infectious diseases, inflammation, and cancer.<sup>13</sup> In 1989, Tanox sought to develop and commercialize its anti-IgE antibodies, and entered into confidential discussions with large, well-financed, and experienced companies, including Genentech and Novartis, to discuss potential collaborations in furtherance thereof.<sup>14</sup> Although Genentech and Tanox discussed a potential collaboration, an agreement was not reached.<sup>15</sup> Instead, in 1990, Tanox entered into a collaborative agreement with Novartis, called the Development & Licensing Agreement (“D&L Agreement”), for the joint development and commercialization of anti-IgE antibody products.<sup>16</sup> Of particular relevance to the parties’ future relationship (and this article) is that under the terms of the D&L Agreement, Tanox had certain rights to develop, independent of the collaboration, any antibody product that Novartis believed was “not sufficiently superior” to justify clinical development under the Tanox-Novartis collaboration.<sup>17</sup>

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<sup>12</sup> Defendant Tanox Inc.’s Memorandum In Support of Its Motion For Preliminary Injunction and Notice of Motion ¶ 5, *Genentech*, No. 99-2060 (May 15, 1999).

<sup>13</sup> “The term IgE refers to a particular class of naturally occurring human immunoglobulin, which is part of the human immune system. Anti-IgE Antibodies refers to a class of molecules that bind to or inhibit the effect of IgE.” Genentech’s Opposition to Tanox’s Motion To Lift Stay of Arbitration at n.1, *Genentech*, No. 99-2060 (Aug. 14, 2000).

<sup>14</sup> Declaration of Dr. Nancy Chang In Support of Defendant’s Motion for Summary Judgment ¶¶ 2–3, *Genentech*, No. 99-2060 (Sept. 18, 2001); see also Annual Report, *supra* note 11, at 10 (stating “We chose to enter into the collaboration agreements with Novartis and Genentech, in part, to secure the benefit of their experience in these areas, as well as the contribution of their greater financial resources.”).

<sup>15</sup> Although none of the parties address the 1989–1990 negotiations in any detail, it is significant that the record suggests that, as early as 1989, discussions occurred between Tanox and Genentech wherein Tanox expressed its desire to have independent development rights in any collaboration. See Joint Statement of Undisputed Facts ¶ 26, *Genentech*, No. 99-2060 (Mar. 14, 2001).

<sup>16</sup> *Id.* ¶ 6.

<sup>17</sup> Specifically, paragraph 5 of Annex 3 of the D&L Agreement provides:

If Tanox desires to pursue development of any Product(s) within the Field, in addition to Product(s) already being developed hereunder, which Ciba-Geigy believes is not sufficiently superior to justify a simultaneous clinical development program, then Tanox itself, without giving rights to any Third Party, will have the right to pursue development of such Product(s) at its sole expense; subject, however, to the right of first refusal of Ciba-Geigy to license the Product(s) as provided under Paragraph 11 of this Agreement.

Joint Statement of Undisputed Facts ¶ 9, *Genentech*, No. 99-2060 (Mar. 14, 2001). It is worth pointing out that the *existence* of Tanox’s independent development rights under the D&L Agreement was not disputed. *Id.* Rather, the *scope* and *extent* of those rights and whether such rights were modified, preempted, or extinguished by subsequent agreements was the primary point of contention among the parties. *Id.* ¶¶ 31, 32; see also Tanox’s Motion for Summary Judgment at 3–8, *Genentech*, No. 99-2060 (Feb. 28, 2001); Genentech’s Motion For Summary Judgment Regarding Contract Issues at 7–12, *Genentech*, No. 99-2060 (Feb. 28, 2001); Plaintiff Novartis Pharma Ag’s Motion For Partial Summary Judgment and Memorandum in Support Thereof at 14–19, *Genentech*, No. 99-2060 (Feb. 28, 2001).

By the early to mid-1990's, the Tanox-Novartis collaboration identified and synthesized two anti-IgE antibodies, designated as CGP 56901 and CGP 51901.<sup>18</sup> The former showed promise in the treatment of peanut allergies (for which it later underwent clinical trials).<sup>19</sup> At the same time, Genentech was developing its own anti-IgE antibodies, E25 and E26.<sup>20</sup> E25 has since obtained the trade name "XOLAIR," and has been approved, marketed, and sold for the treatment of asthma.<sup>21</sup>

In 1993, Genentech approached Novartis and Tanox regarding acquiring Novartis's interest in the Tanox-Novartis collaboration.<sup>22</sup> Although Novartis and Genentech reached an agreement, Tanox and Genentech were unable to do so.<sup>23</sup> Correspondence between Tanox and Genentech during this time period reveals that the failure of the parties to reach an agreement was in significant part a result of Tanox's refusal to relinquish its independent development rights under the D&L Agreement absent considerable compensation.<sup>24</sup>

In late 1993, shortly after Genentech's unsuccessful efforts to purchase Novartis's interest in the Tanox-Novartis collaboration, Tanox sued Genentech and

<sup>18</sup> Joint Statement of Undisputed Facts, *Genentech*, No. 99-2060 ¶ 19 (Mar. 14, 2001).

<sup>19</sup> See Hamilton, *supra* note \*, at A1.

<sup>20</sup> Joint Statement of Undisputed Facts ¶ 9, *Genentech*, No. 99-2060 (Mar. 14, 2001). Note, however, that the parties did *not* agree as to whether Genentech was independently developing its own anti-IgE antibody at any time *prior to* the Tanox-Novartis-Genentech collaboration. Compare Genentech's Motion For Summary Judgment Regarding Contract Issues at 4, *Genentech*, No. 99-2060 (Feb. 28, 2001), with Tanox's Answer to Complaint ¶ 10, *Genentech*, No. 99-2060 (Feb. 28, 2001); see also Complaint of Tanox, Tanox Biosystems v. Genentech, No. H.94-0189 (S.D. Tex. 1993) (Tanox alleging, *inter alia*, that Genentech used confidential information obtained in the 1989-1990 negotiations with Tanox to develop a competing antibody).

<sup>21</sup> Asthma Treatment: Xolair.com, <http://www.xolair.com> (last visited Mar. 24, 2006).

<sup>22</sup> Genentech's Motion For Summary Judgment Regarding Contract Issues at 4-5, *Genentech*, No. 99-2060 (Feb. 28, 2001); Tanox's Motion For Summary Judgment at 1, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>23</sup> Genentech's Motion For Summary Judgment Regarding Contract Issues at 4-5, *Genentech*, No. 99-2060 (Feb. 28, 2001); Tanox's Motion For Summary Judgment at 1, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>24</sup> See Letter from David Anderson, Executive Vice President and General Counsel, Tanox, Inc., to John McLaughlin, Senior Vice President, Genentech (Nov. 29, 1993) (informing Genentech that "Tanox would be willing to give up its parallel development rights in exchange for an agreed cash payment"); Response Letter from John McLaughlin to David Anderson (Dec. 8, 1993) (offering to increase royalties in exchange for limiting Tanox's independent development rights). Both letters were provided to the court. Exhibits in Declaration of Rita A. Hao In Support Of Genentech's Motion For Summary Judgment In Regards to Contract Issues, *Genentech*, No. 99-2060 (Feb. 28, 2001); see also Genentech's Motion For Summary Judgment Regarding Contract Issues at 6, *Genentech*, No. 99-2060 (Feb. 28, 2001).

Genentech dismissed Tanox's suggestion that Genentech and Tanox form a collaboration with independent development rights for Tanox. . . . Tanox responded that it would be willing to "give up" its independent development rights under the D&L Agreement if Genentech paid Tanox \$85 million over five years. Genentech was unwilling to pay such a massive sum. Nor was Genentech willing to enter into a collaboration in which it might have to compete with its supposed collaborator.

*Id.*

others in a Texas federal court, alleging fraud and misappropriation.<sup>25</sup> Tanox alleged, *inter alia*, that Genentech unlawfully used confidential information and samples provided by Tanox during the 1989 negotiations regarding a potential collaboration to develop a competing antibody.<sup>26</sup> In addition, Tanox alleged that Genentech obtained exclusive rights to third party patents in the field of IgE-mediated diseases, which were important for producing antibodies in commercializing quantities, for the sole purpose of hindering Tanox from commercializing its antibodies.<sup>27</sup> In 1994, Genentech countersued Tanox and Novartis claiming that the collaboration's development of anti-IgE antibodies infringed some of Genentech's patents.<sup>28</sup>

In 1996, after more than two years of litigation, the parties settled the matter by agreeing to collaborate and the cases were dismissed.<sup>29</sup> Three settlement agreements ("Agreements") were signed on July 8, 1996: (1) a tripartite agreement, called the "Outline of Terms," wherein the parties agreed to "merge" their respective independent anti-IgE antibody development projects, jointly develop anti-IgE antibodies, and provide each other with royalty free cross licenses for all patents; (2) a bilateral agreement between Tanox and Novartis, called the "Supplemental Agreement;" and (3) a bilateral agreement between Genentech and Tanox called the "Settlement and Cross-Licensing Agreement."<sup>30</sup> The Agreements modified certain

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<sup>25</sup> Roche Holdings and Hoffman-La Roche were also named defendants in the lawsuit as a result of Roche's majority ownership position in Genentech at the time the lawsuit was filed. *Tanox Biosystems v. Genentech*, No. H.94-0189 (S.D. Tex. 1993).

<sup>26</sup> *Id.* A copy of the Complaint was provided as an exhibit to Chang's Declaration. Declaration of Dr. Nancy Chang In Support of Tanox's Motion For Summary Judgment, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>27</sup> *Tanox*, No. H.94-0189 (S.D. Texas. 1993). Because this allegation is never raised in the California litigation, I do not address it. However, if true, such conduct raises considerable antitrust issues.

<sup>28</sup> Plaintiff's Notice Of Motion & Motion To Permanently Stay Arbitration Memorandum of Points and Authorities In Support Thereof at 3, *Genentech*, No. 99-2060 (Apr. 29, 1999). The cases were later consolidated for trial. *Id.*

<sup>29</sup> Plaintiff's Notice Of Motion & Motion To Permanently Stay Arbitration *Genentech*, No. 99-2060 (Apr. 29, 1999); *see also* Plaintiff Novartis AG's Memorandum of Points and Authorities In Opposition To Defendant Tanox's Motion To Lift Stay Of Arbitration at 3, *Genentech*, No. 99-2060 (Aug. 14, 2000); Tanox's Motion For Summary Judgment at 4-5, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>30</sup> Tanox's Motion For Summary Judgment at 4-5, *Genentech*, No. 99-2060 (Feb. 28, 2001). Although not intended to be a final, integrated contract, the Outline of Terms was binding on all parties. Paragraph 13 of The Outline of Terms provides:

13. Binding Nature

The contents of this Outline of Terms represents the bona fide intent of the parties. The parties hereto shall use all reasonable effort to complete the final agreement(s) as referred to in Section 8.2 above as soon as reasonably practicable. It is understood, however, that unless and until the said formal agreement(s) is/are completed and entered into the parties (including their legal successors) shall be legally bound by and shall operate under the terms reflected in the present Outline of Terms, which shall be governed by the laws of the State of New York without regard to conflict of law principles.

Although the Outline of Terms was intended to be supplanted by a more definite, detailed agreement, such an agreement was never made. No party disputes the binding nature of the Outline of Terms. *See Genentech's Opposition To Tanox's Motion To Lift Stay Of Arbitration* at 3-4, *Genentech*, No. 99-2060 (Aug. 14, 2000); *Tanox, Inc's Answer To Complaint For Declaratory Relief*,

rights and obligations under the D&L Agreement and created new ones (particularly as to Genentech, which was not a party to the D&L Agreement), but, significantly, did *not* alter Tanox's independent development rights.<sup>31</sup> Structurally, the Agreements essentially created a joint venture between the parties to develop and commercialize one or more of the four anti-IgE antibodies previously identified and synthesized by the parties.<sup>32</sup> Under the Outline of Terms, the existing anti-IgE projects of both Genentech and the Tanox-Novartis collaboration—which included E25, E26, CGP 56901, and CGP 51901—would merge into a single project.<sup>33</sup> However, notwithstanding the merger of projects, the parties were required to continue to take their respective projects through the FDA Phase II clinical trials.<sup>34</sup> Based on the results of the trials, the parties were to jointly decide, via a “Steering Committee” comprised of all three parties, which of the antibodies would be developed.<sup>35</sup> Thereafter, Novartis and Genentech had the principal obligation for developing, obtaining approval, and commercializing the chosen antibodies (including

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Breach of Contract, Breach of Implied Covenant Of Good Faith and Fair Dealing, Unfair Competition and Misappropriation of Trade Secrets ¶ 13, *Genentech*, No. 99-2060 (May 10, 1999).

<sup>31</sup> Memorandum and Order, *Genentech*, No. 99-2060 (Oct. 9, 2001) (finding, *inter alia*, that Tanox “. . . retained independent development rights under the D&L Agreement after signing the Outline of Terms” and that “. . . the Outline of Terms permits Tanox's use of confidential information in the process of developing rejected antibodies”). In so holding, the Court rejected Novartis and Genentech's argument that provisions of the Outline of Terms, Supplemental Agreement, or Settlement and Cross-Licensing Agreement either expressly or implicitly negated Tanox's independent development rights. *Id.*; see Genentech's Motion For Summary Judgment Regarding Contract Issues at 11–22, *Genentech*, No. 99-2060 (Feb. 28, 2001); Plaintiff Novartis Pharma Ag's Motion For Partial Summary Judgment and Memorandum In Support Thereof at 11–22, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>32</sup> See Genentech's Motion for Summary Judgment Re: Contract issues at 11–22, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>33</sup> A copy of the signed Outline of Terms was provided as an Exhibit to Declaration of Dr. Nancy Chang In Support of Tanox's Motion For Summary Judgment (Feb. 28, 2001), *Genentech*, 99-2060 (Feb. 28, 2001). For purposes of this article, Paragraphs 1 is probably the most significant, and provides:

1. Merger of Anti-IgE Projects

The anti-IgE –antibody projects of Genentech on the one side and Ciba/Tanox on the other side shall be merged, but Genentech and Ciba/Tanox will continue to take their respective anti-IgE antibodies through Phase II clinical trials currently in progress or planned to be performed during 1996. Based upon the results of these trials and other relevant considerations, Genentech, Tanox, and Ciba shall jointly discuss and decide by June 1, 1997 at the latest which of the anti-IgE antibodies shall be taken up in Phase III trials, be developed for additional indications (if any), be submitted for marketing authorization and be commercialized as a pharmaceutical product (“anti-IgE Product”). The final Agreement(s) as referred to in Section 8.2 shall provide for procedures in case of a disagreement between the parties. All development activities shall be supervised by a Steering Committee on which each party is represented. The merging of each party's anti-IgE-antibody project and the development and commercialization thereof according to this Outline of Terms shall extend to all IgE inhibiting antibodies (including fractions or derivatives thereof) which have been identified and synthesized by either party hereto before July 1, 1996.

*Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*



absorbing nearly all of the costs), with Tanox having a substantially limited role.<sup>36</sup> Because the collaboration required sharing of confidential information, the Outline of Terms prohibited disclosure or use of confidential information disclosed in the context of the collaboration's selection, development, or commercialization of the antibody product for any purpose "other than those contemplated under the Outline of Terms."<sup>37</sup> As a final word regarding the 1996 settlement, it is worth mentioning that no provision in any of the Agreements addressed independent development rights despite independent development rights being a material reason for the failures of both the 1989 and 1993 collaborative negotiations between Genentech and Tanox.<sup>38</sup>

During the summer of 1997, the Steering Committee selected the two molecules synthesized by Genentech for further development and commercialization.<sup>39</sup> In addition, it decided that the two molecules developed by the Tanox-Novartis collaboration would no longer be developed.<sup>40</sup> Because the collaboration chose not to develop CGP 56901, and based upon its belief that there was a significant market for

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<sup>36</sup> It appears that Tanox's obligations in the collaboration was primarily limited to licensing its patent rights. In contrast, its rights under the Agreements included limited commercialization and manufacturing rights, and substantial milestone payments and royalties. *See, e.g.*, Outline of Terms ¶¶ 2–5, Supplemental Agreement ¶ 1, Settlement & Cross-Licensing Agreement, attached to Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>37</sup> Paragraph 10.1 of the Outline of Terms provides:

Any information and data disclosed by a party to another party hereto (the 'Receiving Party') in the context of the selection, development, and commercialization of the anti-IgE Product shall be kept strictly confidential by the Receiving Party, shall not be disclosed to any third party by the Receiving Party and shall not be used by the Receiving Party for any purpose other than those contemplated under this Outline of Terms.

Outline of Terms ¶ 10 attached to Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment, *Genentech*, No. 99-2060 (Feb. 28, 2001). Novartis and Genentech argued that this provision prohibited Tanox from using confidential information obtained via the collaboration in its independent development of CGP 56901. Genentech's Opposition To Tanox's Motion For a Preliminary Injunction at 9–10, *Genentech*, No. 99-2060 (Feb. 28, 2001) (Sept. 10, 2001).

<sup>38</sup> The record is not entirely clear regarding the extent of settlement negotiations pertaining to Tanox's independent development rights. The parties assert that no negotiations were held on independent development rights. *See* Tanox's Motion For Summary Judgment at 5, *Genentech*, No. 99-2060 (Feb. 28, 2001); Joint Statement of Undisputed Facts ¶ 26, *Genentech*, No. 99-2060 (Feb. 28, 2001). However, the parties also acknowledge that several drafts of the Outline of Terms were circulated, some of which made explicit references to Tanox's rights under the D&L Agreement (which would include any independent development rights included therein). Joint Statement of Undisputed Facts ¶¶ 17–19, *Genentech*, No. 99-2060 (Feb. 28, 2001); Genentech's Motion For Summary Judgment Regarding Contract Issues at 9–10, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>39</sup> Joint Statement of Undisputed Facts ¶ 29, *Genentech*, No. 99-2060 (Feb. 28, 2001); *see also* Minutes from Genentech-Tanox-Ciba Anti-IgE Joint Steering Committee (Oct. 18, 1996) attached to Declaration of Nancy Chang In Support of Defendant Tanox's Motion For Summary Judgment, *Genentech*, No. 99-2060 (Feb. 28, 2001) (Wherein the Steering Committee accepts the recommendation to select XOLAIR for further development, but agrees with the recommendation for "manufacturing and clinical programs for CGP 56901 until Q2 '97 as a back-up plan if it is necessary to switch back to CGP 56901").

<sup>40</sup> *See* Letter from Dr. Herbert Gut, Novartis, to David Anderson, Tanox, (Sept. 20, 1997) attached to Declaration of Rita Hao In Support of Genentech's Motion For Summary Judgment Regarding Contract Issues, *Genentech*, No. 99-2060 (Feb. 28, 2001).

an anti-IgE antibody product for the treatment of peanut allergies, Tanox began to independently develop CGP 56901—a right Tanox believed it had under the D&L Agreement and retained after signing the Agreements.<sup>41</sup> Genentech and Novartis, however, disapproved, and strongly contested that Tanox had any right to develop CGP 56901 outside of the collaboration.<sup>42</sup> For over a year the parties negotiated in an attempt to resolve their disputes over Tanox's rights to independently develop CGP 56901. Tanox also sought mediation and arbitration pursuant to dispute resolution provisions in the D&L Agreement and Settlement & Cross-Licensing Agreement.<sup>43</sup> However, in April 1999, shortly after Tanox filed for arbitration, Genentech and Novartis filed a lawsuit in federal district court in San Francisco to cease Tanox's development and commercialization of CGP 56901.<sup>44</sup> In addition,

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<sup>41</sup> Tanox explains its reason for independent development of CGP 56901:

As indicated in our Demand for Arbitration, especially on pages 10 and 13, Tanox has tried regularly to convey its intentions for the exercising of its independent development rights. As you by now should be well aware, we are pursuing clinical development activities in patients allergic to peanuts. We continue to have an interest in the area of atopic dermatitis as we previously stated, and to the extent permitted by the express terms of our agreement as determined in our arbitration proceedings, we will continue to look for other areas where Novartis and Genentech have not shown sufficient commitment to development and commercialization to persuade us that our efforts are either unnecessary or not cost effective. As we have repeatedly stressed, we believe the market for anti-IgE antibodies is far greater than suggested by Novartis' market assessments and what we believe to be its inadequate commitment to product supply.

Letter from David Anderson, Tanox, to Dr. Herbert Gut, Novartis (Apr. 29, 1999). From 1999–2002, Tanox conducted clinical trials of CGP 56901 for use against peanut allergies. According to a study published in the March 13, 2003 edition of the *New England Journal of Medicine*, the trials were promising, with all patients on the drug showing a decrease in their IgE levels at the end of the study. See *Anti-IgE Therapy Update*, <http://www.foodallergy.org/Research/antiigetherapy.html> (last visited Apr. 23, 2006).

<sup>42</sup> CGP 56901, the back-up molecule that Tanox is now unilaterally developing, was identified before July 1, 1996, and is therefore subject to the exclusive supervision of the steering committee established by the Outline of Terms. Accordingly, Tanox has no right to develop CGP 56901 by itself, having given up that right in exchange for a sizable sum of money; assistance in research, development, and marketing of its products; and continuing royalty rights in any product developed by the three-way collaboration of the companies.

Genentech's Motion For Summary Judgment Regarding Contract Issues at 2, *Genentech*, No. 99-2060 (Feb. 28, 2001); see also Genentech-Novartis-Tanox Joint Steering Committee Anti IgE Minutes (Aug. 14, 1997) attached to Declaration of Nancy Chang In Support of Tanox's Reply In Support Its Motion For Preliminary Injunction, *Genentech*, No. 99-2060 (Feb. 28, 2001) (Wherein Genentech and Novartis dispute Tanox's claimed independent development rights.).

<sup>43</sup> Declaration of Nancy Chang In Support of Tanox's Reply In Support of Its Motion For Preliminary Injunction at Ex. 6, *Genentech*, No. 99-2060 (Sept. 18, 2001) (requesting mediation in a January 29, 1999 letter from Jeffrey Parson, Esq., Outside Counsel for Tanox, to Dana Haviland, Outside Counsel for Genentech, and Genentech's Feb. 8, 1999 response, denying the request). In February 1999, Tanox filed a demand for arbitration against Novartis. Genentech's Opposition to tanox's Motion to Lift Stay of Arbitration at 3, *Genentech*, No. 99-2060 (Aug. 14, 2000). In July 1999, Tanox filed for arbitration against Genentech. *Id.*

<sup>44</sup> Memorandum and Order at 1, 11, *Genentech*, No. 99-2060 (Oct. 9, 2001). The Complaint was filed on April 29, 1999. Complaint for Declaratory Relief, Breach of Implied Covenant of Good Faith and Fair Dealing, Unfair Competition and Misappropriation of Trade Secrets at 1, *Genentech*, No. 99-2060 (Apr. 29, 1999). By order of the Court on September 3, 1999, the arbitration was stayed

Tanox was informed that it would be unable to attend meetings of the Steering Committee or have access to confidential information regarding the development of XOLAIR unless it agreed that any information it obtained from the collaboration would not be used in its development of a competing drug.<sup>45</sup>

The primary substantive issues disputed in the lawsuit were the existence and scope of Tanox's rights to independently develop CGP 56901 and its use of confidential information obtained in the collaboration.<sup>46</sup> Tanox asserted that both its right to independent development of CGP 56901 and to use information obtained from the collaboration in its development of CGP 56901 were expressly provided for in the D&L Agreement, and that these rights were unaltered by the Agreements.<sup>47</sup> In contrast, Genentech and Novartis averred that Tanox's independent development rights under the D&L Agreement were far more limited than Tanox claimed, and moreover, were "extinguished" or "preempted" by the Agreements.<sup>48</sup> Genentech also argued that Tanox's used confidential information that it obtained from the collaboration, thus not only violating the confidentiality provision of the Outline of Terms, but also constituting trade secret misappropriation and unfair competition.<sup>49</sup> No antitrust claims were raised in the lawsuit.<sup>50</sup>

After several years of litigation and an unsuccessful court ordered mediation, the district court held that the Agreements did not extinguish Tanox's independent development rights under the D&L Agreement, and held that Tanox had the right to

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and mediation was ordered. Memorandum and Order at 1, 11, *Genentech*, No. 99-2060 (Oct. 9, 2001). By order of the Court on October 9, 2001, the stay was lifted. *Id.*

<sup>45</sup> Defendant Tanox Inc.'s Memorandum In Support of Its Motion For Preliminary Injunction and Notice of Motion at 7, *Genentech*, No. 99-2060 (Aug. 15, 2001); *see also* Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment, *Genentech*, No. 99-2060 (Feb. 28, 2001) (regarding a letter from David Anderson, Tanox, to Dr. Herbert Gut and Dr. Djordje, Novartis, dated September 10, 1999 about Novartis's refusal to permit Tanox to attend the Steering Committee meetings or have access to confidential information, and regarding the response from Dr. Gut dated September 14, 1999).

<sup>46</sup> Genentech's Motion for Summary Judgment Regarding Contract Issues at 3, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>47</sup> Defendant Tanox's Opposition to Genentech's Motion for Summary Judgment in Regard to Contract Issues at 2, *Genentech*, No. 99-2060 (Mar. 14, 2001).

<sup>48</sup> Genentech's Motion for Summary Judgment Regarding Contract Issues at 2, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>49</sup> Genentech's Opposition To Tanox's Motion To Lift Stay of Arbitration at 4-5, *Genentech*, No. 99-2060 (Aug. 14, 2000); Genentech's Opposition To Tanox's Motion For A Preliminary Injunction at 10-11, *Genentech*, No. 99-2060 (Sept. 10, 2001) (arguing that the confidential information Plaintiffs were trying to protect were trade secrets, which they are required by law to protect or forfeit, and which Defendant misappropriated).

<sup>50</sup> Defendant Tanox's Opposition to Genentech's Motion for Summary Judgment in Regard to Contract Issues at 10, *Genentech*, No. 99-2060 (Mar. 14, 2001). In fact, the only statement found regarding antitrust liability during the entire litigation was the following brief statement by Tanox:

It was not the intent of this collaborative effort to stifle competition but, rather, to jointly develop a novel therapeutic treatment and thereby share the risk inherent in developing new pharmaceuticals. One of the lead negotiators for Novartis privately expressed the view that competition with a jointly developed anti-IgE product might enhance the market and benefit all. Even when the agreements were signed on July 8, 1996, the parties were clearly permitted to compete with the new collaboration as antibodies identified after July 1, 1996 (a week before the agreements were signed) were not even candidates or joint development by the collaboration.

*Id.*

use confidential information obtained from the collaboration in the development of antibodies rejected by the collaboration.<sup>51</sup> However, the court also declared that the extent and scope of Tanox's independent rights, in particular whether such rights encompassed development of CGP 56901 outside of the collaboration, were subject to arbitration.<sup>52</sup> On February 25, 2004, after an arbitrator ruled against Tanox's right to independently develop CGP 56901, the parties settled the case.<sup>53</sup> As a result of the settlement, Tanox ceased developing CGP 56901 and gave up certain rights it had under the Agreements (most substantially, all manufacturing rights) in exchange for increased royalties, milestone payments, a one time \$6.6 million dollar payment to cover a portion of the development costs of CGP 56901, and loan forgiveness from Novartis worth over \$10 million dollars.<sup>54</sup> In addition, after the settlement, the collaboration announced that it would test XOLAIR for use against peanut allergies.<sup>55</sup> The Phase II clinical trials began in June 2004, but were terminated in January 2006 because of purported safety concerns with the allergy test used in the trials.<sup>56</sup> As a result, it is likely that obtaining FDA approval for use of XOLAIR in treating allergies remains years away.<sup>57</sup>

At least 1.5 million people living in the United States have nut allergies, and some can die within minutes if accidentally exposed.<sup>58</sup> According to a study published in the December 2003 *Journal of Allergy and Clinical Immunology*, the number of reported peanut allergies in children doubled between 1997 and 2002 from .4% to .8%.<sup>59</sup>

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<sup>51</sup> Memorandum and Order, *Genentech*, No. 99-2060 (Oct. 9, 2001) (granting defendant's motion for summary judgment, and denying plaintiff's motion for summary judgment).

<sup>52</sup> Memorandum and Order at 11, *Genentech*, No. 99-2060 (Oct. 9, 2001) (granting defendant's motion to lift stay of arbitration); see also Transcripts of Hearing, *Genentech*, No. 99-2060 (Dec. 10, 2001) (clarifying the Court's Oct. 9, 2001 Order and staying all legal proceedings pending arbitration).

<sup>53</sup> Annual Report, *supra* note 11, at 35. On February 25, 2004, the parties entered into a new agreement, the Tripartite Collaboration Agreement, "to settle all then outstanding litigation and arbitrations among the parties and to finalize the detailed terms of the three-party collaborations." *Id.* A stipulation for voluntary dismissal was submitted to the court on February 27, 2004, and on March 5, 2004, by order of the Court, the case was dismissed. Unfortunately, the February 25, 2004 settlement agreement was not provided in the record, or otherwise publicly disclosed, so its terms are unknown to the author.

<sup>54</sup> See Annual Report, *supra* note 11, at 6-7, 32, 35; see also Novartis, Genentech, and Tanox settle dispute surrounding Xolair and TNX-901, [http://dominoext.novartis.com/NC/NCMediaRel9798.nsf/0/49f369fb415e136ec1256f8000421b40/\\$FILE/PR%20XOLAIR%20Settlement%2026.02.04.pdf](http://dominoext.novartis.com/NC/NCMediaRel9798.nsf/0/49f369fb415e136ec1256f8000421b40/$FILE/PR%20XOLAIR%20Settlement%2026.02.04.pdf) (Feb. 26, 2003) (announcing the settlement).

<sup>55</sup> Novartis, Genentech, and Tanox settle dispute surrounding Xolair and TNX-901, [http://dominoext.novartis.com/NC/NCMediaRel9798.nsf/0/49f369fb415e136ec1256f8000421b40/\\$FILE/PR%20XOLAIR%20Settlement%2026.02.04.pdf](http://dominoext.novartis.com/NC/NCMediaRel9798.nsf/0/49f369fb415e136ec1256f8000421b40/$FILE/PR%20XOLAIR%20Settlement%2026.02.04.pdf) (Feb. 26, 2003).

<sup>56</sup> See Annual Report, *supra* note 11, at 4; David Hamilton, *Genentech Stops Trial on Concerns over Safety of Peanut-Allergy Test*, WALL ST. J., Jan. 16, 2006.

<sup>57</sup> Hamilton, *supra* note 56.

<sup>58</sup> The Food Allergy and Anaphylaxis Network, <http://www.foodallergy.org/whatsnew.html> (last visited Apr. 23, 2006); Hamilton, *supra* note \*, at A1.

<sup>59</sup> *Study Confirms What Doctors and Parents Have Suspected: Peanut Allergies in Children Have Doubled in the Last Five Years Food Allergies and Anaphylaxis Network Seeks Higher Standards of Care*, [http://allergies.about.com/gi/dynamic/offsite.htm?zi=1/XJ&sdn=allergies&z=http%3A%2F%2Fwww.foodallergy.org%2Fpress\\_releases%2Fprevalence.html](http://allergies.about.com/gi/dynamic/offsite.htm?zi=1/XJ&sdn=allergies&z=http%3A%2F%2Fwww.foodallergy.org%2Fpress_releases%2Fprevalence.html) (Dec. 9, 2003).

## II. ANTITRUST LAW

This article examines anticompetitive concerns presented by the Novartis-Genentech-Tanox relationship and particularly, resulting from the tripartite collaboration. As a matter of policy, competition in markets is generally considered desirable for the following reasons: (1) competition tends to lead to increased output and decreased prices, benefiting consumers; (2) competition generally results in increased allocative and productive efficiency; (3) competition tends to create incentives to innovate; and (4) in industries where firms produce differentiated goods, competition tends to lead to enhanced variety.<sup>60</sup> In the United States, the principle statutory basis for regulating conduct which harms competition is the Sherman Antitrust Act (“Sherman Act”).<sup>61</sup> Accordingly, this section will begin with a brief overview of the Sherman Act, followed by a more detailed antitrust analysis of issues particularly relevant to this article: collaboration among competitors, settlement of patents disputes, and the acquisition and non-use of patents.

### *A. The Sherman Antitrust Act: A Basic Overview*

Section 1 of the Sherman Act prohibits agreements or other joint firm conduct which “unreasonably” restrains trade.<sup>62</sup> Case law has interpreted the reasonableness criteria as assessing the effect of the challenged conduct on competition.<sup>63</sup> Consequently, when determining whether any particular conduct unreasonably restrains trade, courts and enforcement agencies generally examine and weigh the anticompetitive effects of the conduct against all genuine pro-competitive justifications.<sup>64</sup> This inquiry, termed the “rule of reason” in antitrust parlance, is

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<sup>60</sup> LAWRENCE SULLIVAN & WARREN GRIMES, *THE LAW OF ANTITRUST: AN INTEGRATED HANDBOOK*, § 1.5(b) (2000); *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958).

The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions. But even were that premise open to question, the policy unequivocally laid down by the Act is competition.

*N. Pac. Ry. Co.*, 356 U.S. at 4; see also The UK’s Department of Industry’s July 2001 White Paper, *Productivity and Enterprise: A World Class Competition Regime* § 1.1, *available at* <http://www.archive.official-documents.co.uk/document/cm52/5233/523304.htm> (“Vigorous competition between firms is the lifeblood of strong and effective markets. Competition helps consumers get a good deal. It encourages firms to innovate by reducing slack, putting downward pressure on costs and providing incentives for the efficient organisation of production.”).

<sup>61</sup> Sherman Act, 15 U.S.C. § 1 *et seq.* (2000).

<sup>62</sup> Sherman Act, 15 U.S.C. § 1. Section 1 provides in part: “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.” *Id.*

Despite its broad prohibitive terms, it has long been held that Section 1 only condemns “unreasonable” restraints. *See, e.g., Standard Oil v. United States*, 221 U.S. 1, 87 (1911).

<sup>63</sup> *Standard Oil*, 221 U.S. at 87.

<sup>64</sup> *Id.*

both flexible and fact specific, and usually requires an assessment of the relevant industry, the firms involved in the litigation, the nature of the restraint, the valid pro-competitive justifications for the restraint (e.g. efficiencies), and the actual and likely effects of the restraint on both the industry (which includes potential entrants as well as current firms) and consumers.<sup>65</sup> Because this analysis is extensive, costly, and time consuming, courts have articulated circumstances when the analysis can be truncated or even obviated.<sup>66</sup> For example, it has long been held that certain types of conduct are so likely to be harmful to competition and to have no significant pro-competitive benefit that such conduct may be condemned outright, and held to be per se illegal without any assessment of particular effects.<sup>67</sup> Alternatively, conduct that is not deemed per se illegal but nevertheless “appears likely, absent an efficiency justification, to restrict competition and decrease output” may be presumed to be unreasonable without a detailed market analysis, although such presumption is rebuttable upon plausible and legally cognizable pro-competitive justification(s) for the conduct.<sup>68</sup>

Section 2 of the Sherman Act proscribes “monopolization” and attempted monopolization.<sup>69</sup> Monopolization has two elements: “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”<sup>70</sup> Various types of conduct may fall within the ambit of monopolization including predation (price and non-price), price squeezing, tying, bundling, exclusive dealings, and refusals to deal.<sup>71</sup>

Although distinct, both section 1 and section 2 of the Sherman Act attempt to regulate conduct which is likely to harm competition and, ultimately, consumers.<sup>72</sup>

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<sup>65</sup> See WILLIAM HOLMES, ANTITRUST LAW HANDBOOK § 2.10 (2006 Ed.).

<sup>66</sup> N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958).

<sup>67</sup> *Id.* “[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without any elaborate inquiry as to the precise harm they have caused or the business excuse for their use.” *Id.*; see also FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm> (issued jointly by the Federal Trade Commission and Department of Justice). The most common types of per se illegal acts are price fixing, bid rigging, and market allocations. *Id.*

<sup>68</sup> Polygram Holding, Inc. v. FTC, 416 F.3d 29, 33 (D.C. Cir. 2005). This type of analysis is generally termed a “quick look” analysis. See also, California Dental Ass’n v. FTC, 526 U.S. 756 (1999); FTC v. Ind. Fed’n of Dentists, 476 U.S. 447 (1986).

<sup>69</sup> Sherman Act, 15 U.S.C. § 2 (2000). Section 2 of the Sherman Act provides:

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

*Id.*

<sup>70</sup> United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

<sup>71</sup> JULIAN VON KALINOWSKI ET AL., ANTITRUST LAWS AND TRADE REGULATION: DESK EDITION § 3.02(3) (2d ed.).

<sup>72</sup> It is fairly well established in modern U.S. antitrust jurisprudence that for conduct to be “anticompetitive,” it must adversely affect *consumers*; that is, the conduct will result, or is likely to

Harm to competition may be shown directly, e.g., demonstrating that the conduct restricted output or increased prices, or indirectly.<sup>73</sup> When anticompetitive harm is not obvious from the nature of the conduct or its actual effects, courts generally require an initial assessment as to whether the party engaging in the challenged conduct has monopoly power (also called “market power”) in some properly defined “relevant market.”<sup>74</sup> Market power has been defined as “the power to control prices or exclude competition” in some relevant market,<sup>75</sup> or the ability of a firm to “profitably raise prices substantially above the competitive level.”<sup>76</sup> The justification for evaluating market power of the firm engaging in the challenged conduct in a properly defined market is to prevent overly aggressive antitrust enforcement which may benefit competitors rather than consumers.<sup>77</sup> That is, absent sufficient market power, conduct will not likely have an adverse effect on competition.<sup>78</sup>

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result, in consumer harm, not merely harm to competitors. *See, e.g.*, Spanish Broad. of Fla. v. Clear Channel Commc’n, 376 F.3d 1065, 1071 (11th Cir. 2004); Dickson v. Microsoft, 309 F.3d 193, 206 (4th Cir. 2002); United States v. Microsoft, 253 F.3d 34, 58 (D.C. Cir. 2001); Augusta News Corp. v. Hudson News, 269 F.3d 41, 47 (1st Cir. 2001); KMB Warehouse Distrib. v. Walker Mfg., 61 F.3d 123, 127 (2nd Cir. 1995); *see also* PHILIP AREEDA & HERBERT HOVENKAMP, FUNDAMENTALS OF ANTITRUST LAW § 6.04(d) (3d ed. 2004).

<sup>73</sup> Fed. Trade Comm’n v. Ind. Fed’n of Dentists, 476 U.S. 447 (1986).

<sup>74</sup> Defining a “relevant market” generally requires characterization and a determination as to the products and services involved and the geographical area in which firms offering the defined product or service compete. Although market power is not a required element under the traditional rule of reason analysis, recently many courts have made it a *de facto* element. *See* E. Food Serv. v. Pontifical Catholic Univ. Serv. Ass’n, 357 F.3d 1 (1st Cir. 2004); United States v. Visa, Inc., 344 F.3d 229, 238 (2nd Cir. 2003); Maris Distrib. Co. v. Anheuser Bush, 302 F.3d 1207 (11th Cir. 2002); Cont’l Airlines v. United Airlines, 277 F.3d 499 (4th Cir. 2002); Chi. Prof’l Sports Ltd. P’ship v. Nat’l Basketball Ass’n, 95 F. 3d 593, 600 (7th Cir. 1996); Rothery Storage & Van Co. v. Atlas Van Lines, 792 F.2d 210, 229 (D.C. Cir. 1985); *see also* HOLMES, *supra* note 65, § 2.10.

<sup>75</sup> United States v. E.I. Du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

<sup>76</sup> United States v. Microsoft, 253 F.3d 34, 51 (D.C. Cir. 2001). Market power can be shown either directly, e.g., by showing actual harm which could not occur but for such power, or may be inferred by providing evidence demonstrating that the firm has a dominant share of a relevant market which is characterized by significant entry barriers. *Id.* Because nearly all firms have some ability to profitably raise prices above what would be expected under a “perfectly competitive” market, the extent of market power is dependent in part upon the definition of a relevant market. Thus, defining a relevant market provides a context in which to evaluate the challenged restraint’s effect on competition. Although the term implies a singular market, it is more properly considered the conjunction of two separate markets: (1) a product market, which consists of all products which compete with those products on which the challenged restraint is made; and (2) a geographic market, which helps evaluate the extent of power a firm has by defining the narrowest geographic area in which an increase in price would be profitable. *See also* United States v. Grinnell Corp., 384 U.S. 563, 586 (1966). For a thorough analysis of how courts define the relevant market, *see* SULLIVAN & GRIMES, *supra* note 60, § 2.6(b).

<sup>77</sup> SULLIVAN & GRIMES, *supra* note 60, § 2.1.

Antitrust is concerned with the power of market participants to distort the competitive process. This distortion can misallocate resources, transfer wealth from consumers and other protected groups to market participants with power, or stifle new entry or innovation and commercialization. Without power, a market participant can do none of these things but is, instead, itself subject to the discipline of competition.

*Id.*

<sup>78</sup> *Id.*

### *B. Collaboration Among Competitors*

Modern antitrust jurisprudence views collaborations among competitors, also called horizontal joint ventures,<sup>79</sup> with optimism tempered with cautious reserve. This ambivalence stems from the general belief that such arrangements between competitors often have both significant competitive and anticompetitive potential.<sup>80</sup> As succinctly stated in a popular treatise:

Joint ventures have often proved troublesome for the courts. On the one hand, these arrangements can serve highly desirable competitive objectives, as, for example, by enabling small market participants to pool their resources and become a more effective competitive force, or by facilitating research or product development that might not otherwise occur. On the other hand, concentrating too much power in the hands of those controlling a joint venture can create significant competitive hazards. In particular, the venture may be misused as a subterfuge to impose illegal competitive restraints on the venturers themselves, or may have the effect of foreclosing competitors from a vital resource or market.<sup>81</sup>

When firms combine resources, information, and expertise, consumers may benefit as a result of a decrease in prices, increase in output, or enhanced innovation.<sup>82</sup> Of course, certain agreements among competitors may be a disguised effort to increase prices, allocate markets, decrease output, or stifle innovation, and will be denounced as unlawful despite the “collaboration” or “joint venture” nomenclature.<sup>83</sup> However, even where the collaboration as a whole is either

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<sup>79</sup> For purposes of antitrust, “joint venture” has never been officially defined by statute, guidelines, or by the U.S. Supreme Court although several treaties have given varied definitions. *See, e.g.*, AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 2100 (2d ed. 2005); EARL W. KINTNER ET AL., FEDERAL ANTITRUST LAW, § 11.32 (2004). Although some may define a “joint venture” as a type of collaboration requiring significant integration between the firms, this article uses the term collaboration and joint venture synonymously. “Horizontal” is used to indicate that the joint venture is comprised of firms which compete against each other in some market. In contrast, “vertical” joint ventures, consisting of firms which do not compete, operate at different levels of production, e.g. manufacture, retail, and distribution.

<sup>80</sup> HOLMES, *supra* note 65, § 2.25.

<sup>81</sup> *Id.*

<sup>82</sup> Of course, whether the firms will *pass on* to consumers any cost reducing savings or innovative efficiencies achieved by the joint venture is another issue. When the industry is competitive, with the joint venture having little market power, the hope is that the market will force prices down, causing at least some of the cost savings and innovative efficiencies to be passed on to consumers. Similarly, it should be noted that not all cost savings are efficient.

A cost reduction is efficient when it permits the firm to produce the same output at lower cost, or achieves cost reductions that exceed corresponding output reductions. [For example, a]n agreement not to innovate reduces immediate costs but also reduces the long-run benefits of innovation. Such an agreement is anticompetitive if it eliminates innovations that would have been cost justified in a competitive innovation market.

PHILLIP AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2115(b) (2d ed. 2005).

<sup>83</sup> “[L]abeling an arrangement a ‘joint venture’ will not protect what is merely a device to raise prices or restrict output . . . the nature of the conduct, not its designation, is determinative.” FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg.



necessary for a product to exist or entails significant cost savings, particular restraints imposed may be anticompetitive.<sup>84</sup> In these cases, modern antitrust analysis generally evaluates the following: (1) the purpose and nature of the restraint(s); (2) the anticompetitive effect, or potential effect, of the restraints; and (3) whether the restraints are reasonably necessary for the achievement of the pro-competitive purpose of the collaboration.<sup>85</sup> Accordingly, an analysis of both the collaboration as a whole, as well as any potentially anticompetitive restraints imposed by the collaboration, may be warranted. Because of the likelihood of finding both pro-competitive and anti-competitive effects, joint ventures are generally evaluated under the extensive “rule of reason” analysis.<sup>86</sup> However, the potential pro-competitive benefits will neither shield a collaboration, nor a particular restraint, from being condemned as per se illegal in those cases where the facts and circumstances evince that per se treatment is appropriate.<sup>87</sup>

Cognizant of the ambivalent and inconsistent judicial attitude towards competitor collaborations, federal agencies authorized to enforce the Sherman Act

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Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm> (citation omitted).

<sup>84</sup> *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 351 (1982); *Cal. Dental Ass’n v. FTC*, 526 U.S. 756 (1999); *Polygram Holding Inc. v. FTC*, 416 F.3d 29, 38 (D.C. Cir. 2005). Cases involving the National Collegiate Athletic Association are also good examples. See, e.g., *Law v. NCAA*, 134 F.3d 1010, 1023 (10th Cir. 1998). Despite finding that the collaboration is lawful, certain restrictions imposed by the organizations have been found unlawful. See, e.g., *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 110, n.39 (1984); *Law v. NCAA*, 134 F.3d at 1010.

<sup>85</sup> Gregory Werder, *Antitrust Analysis of Joint Ventures: An Overview*, 66 ANTITRUST L.J. 701, 707 (1998).

A collateral restraint may be reasonably necessary to the achievement of the efficiency-enhancing purposes of a joint venture in a variety of ways. A collateral restraint may make the venture itself operate more efficiently, as might a requirement that joint venture participants buy exclusively from a manufacturing joint venture, in order to facilitate the realization of economies of scale. A collateral restraint may prevent a participant in a joint venture from appropriating an undue share of the venture's benefits, as might exclusive distribution territories for a brand created and promoted by a joint venture. A collateral restraint may prevent non-participants from appropriating joint venture benefits for which they have not shared the costs, as might restrictions on resale of a joint venture's output to non-participants. A collateral restraint may also prevent unintended competitive consequences that might make the venture uneconomic.

*Id.*

<sup>86</sup> EARL W. KINTNER ET AL., FEDERAL ANTITRUST LAW, § 11.32 (2004); FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 1.2, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>87</sup> *Maricopa County Med. Soc’y*, 457 U.S. at 351; *Timken Roller Bearing v. United States*, 341 U.S. 593, 598 (1951); *Engine Specialties v. Bombardier LTD*, 605 F.2d 1, 19 (1st Cir. 1979).

At the outset, we observe that joint ventures without more, are judged against the standard of reasonableness rather than the per se rule. However, the nomenclature ‘joint venture’ does not automatically exempt a combination from the per se rule which is found to have elements inherently offensive to the antitrust laws.

FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors ex.4, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

jointly issued guidelines explaining their approach for examining such collaborative efforts among competitors.<sup>88</sup> Although only guidelines, *Antitrust Guidelines for Collaboration Among Competitors* is both helpful and consistent with modern antitrust case law.<sup>89</sup> In these guidelines, the agencies explain their methodology for assessing whether a collaboration or particular restraint harms competition.<sup>90</sup> To summarize, the agencies first examine the nature and purpose of the collaboration or restraint, and whether anticompetitive harm has occurred or is likely to occur as a result of the collaboration or restraint.<sup>91</sup> If this initial assessment presents significant concerns of anticompetitive harm, the agencies will conduct a more detailed analysis unless it deems the collaboration or restraint to be per se illegal.<sup>92</sup> The detailed analysis includes defining the relevant market; measuring market shares and concentrations; evaluating the ease and competitive effect of entry; and examining factors relevant to the extent to which the participants and the collaboration have the ability and incentive to compete independently.<sup>93</sup> If this examination leads the agencies to believe that anticompetitive harm is likely, the agencies will evaluate the pro-competitive efficiencies of the collaboration: (1) whether the pro-competitive benefits are reasonably necessary to achieve the claimed benefits (including the existence of less anticompetitive alternative to achieve the claimed benefits);<sup>94</sup> and (2) whether the pro-competitive justifications are sufficient to offset the anticompetitive harm.<sup>95</sup>

### C. Settlements of Patent Disputes

Although generally favored by an over-burdened judiciary, settlements which result in former competitors agreeing not to compete may be anticompetitive.<sup>96</sup> In recent years, settlements resulting from patent disputes have been controversial, particularly those in the pharmaceutical industry.<sup>97</sup> In many of these cases, anticompetitive issues emanate via settlements between a company with a branded, patented drug and a company introducing a generic alternative.<sup>98</sup> Especially controversial have been so-called “reverse” payments from a branded manufacturer

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<sup>88</sup> See FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 1.1, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>89</sup> Compare *id.* § 1.2 (discussing two types of analysis used to determine lawfulness of an agreement among competitors), with *Nat’l Soc’y of Prof’l Engr’s v. United States*, 435 U.S. 679, 692 (1978) (describing the difference “illegal per se” and rule of reason analyses).

<sup>90</sup> See FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.3, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* § 3.34.

<sup>94</sup> *Id.* § 3.36.

<sup>95</sup> *Id.* § 3.37.

<sup>96</sup> *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2005).

<sup>97</sup> *Id.*; see also *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (2005).

<sup>98</sup> See, e.g., *Tamoxifen*, 429 F.3d 370 (2005); *Schering-Plough*, 402 F.3d 1056 (2005).

to a generic entrant (or potential entrant) in exchange for delayed or foregone entry.<sup>99</sup> Some have argued that such agreements should be condemned as a per se illegal market allocation among competitors.<sup>100</sup> Others have retorted that because a patent is involved, the agreement may be a permissible right granted under patent law, or at the very least, are not so clearly anticompetitive as to be condemned without a detailed analysis of the purpose of the settlement, validity of the patent, and likely result of litigation.<sup>101</sup> For example, the authors of the prominent treatise, *Antitrust Law*, have opined that assuming a bona fide dispute over patent rights, a settlement resulting in a market allocation effectuated by cross-licensing of the very patents whose validity and infringement are in question may be no more anticompetitive than a final result granting a patent monopoly to one party.<sup>102</sup>

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<sup>99</sup> See, e.g., *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d (E.D.N.Y. 2003) ("rule of reason" test applied to Sherman Act restraint claim arising out of agreement under which prospective manufacturers of generic version of a drug agreed to defer entry into generic market until after expiration of patent, in return for payments from brand name manufacturer).

<sup>100</sup> *Ciprofloxacin*, 261 F. Supp. 2d at 256–57.

<sup>101</sup> *Id.* There have been many excellent articles discussing the antitrust concerns raised by such issues. See generally Deborah Coleman, *Antitrust Issues in the Litigation and Settlement of Infringement Claims*, 37 AKRON L. REV. 263 (2004); Marc Schildkraut, *Patent Splitting Settlement and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Herbert Hovenkamp, Mark Janis & Mark Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON. L. REV. 359 (2002); Daniel Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002); David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000); see also Dep't of Justice & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 5.5 (1995) (regarding settlements of patent disputes involving cross licensing agreements).

<sup>102</sup> 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046.

Suppose that A and B have developed potentially conflicting patents for a superior memory device. A claims that B's practice of its patent to make the device infringes on A's patent; B makes the same claim in reverse. The parties begin litigation, but contemplating a long and uncertain path they instead compromise their differences by an agreement that A will manufacture its memory device only in a format to be used by IBM-compatible computers, and B will manufacture its memory device only in a format for use in Apple computers. Formally, this agreement may include a cross-license—that is, A licenses B to use A's patent and B licenses A to use A's patent. Of course, these are cross-"licenses" of patents that both licensees assert are invalid, but the whole point of the settlement is to avoid the cost of litigation that might ultimately determine validity.

This scenario poses a dilemma, notwithstanding our general wish to encourage settlement. First, in the absence of intellectual property rights the agreement in question would be a per se unlawful market division and perhaps even a criminal violation. Second, there is sufficient doubt about the validity or applicability of both patents that each patentee preferred to settle rather than litigate to a decision. Third, a likely outcome of the fully litigated dispute would be a declaration that one firm's patent is invalid, thus yielding the entire market to the other firm; the settlement is certainly no more anticompetitive than that possible outcome and, depending on the circumstances, may be considerably less anticompetitive in that it preserves both firms in the market.

*Id.*

In addition to the complexities arising from whether these types of settlements should be lawful given the underlying patent rights, another complication is the issue of possible antitrust immunity granted for petitioning government under the so-called *Noerr-Pennington* doctrine.<sup>103</sup> As a result, it is little surprise that courts have been less than consistent in how they have analyzed and treated patent settlements with “reverse” payments.<sup>104</sup> However, regardless of the legality of these types of agreements such as with the 1996 Tanox-Novartis-Genentech settlement discussed, the effect of precluding or forestalling competing products from the market may have a substantial and serious impact on consumers—particularly in an area as important as health care.

#### *D. Patent Acquisition and Nonuse*

In general, acquisition and non-use of a patent is not unlawful. A patent holder may use, license, or shelve an invention as he or she pleases: “A patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention. He has no obligation either to use it or to grant its use to others.”<sup>105</sup> However, both case law and commentary evince that acquisition and non-use of patents may be unlawful if either (1) done unilaterally by a firm with market power as a means of obtaining or maintaining power in a relevant market; or (2) done as part of a collaborative effort with the purpose and effect of harming competition.<sup>106</sup>

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<sup>103</sup> See *supra*, note 101. The aforementioned cited articles discuss the controversy regarding when and to what extent *Noerr-Pennington* immunity should apply and has been applied. See also *Ciprofloxacin*, 261 F. Supp. 2d at 212.

<sup>104</sup> Compare *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2nd Cir. 2005), with *Schering Plough v. Fed. Trade Comm’n*, 402 F.3d 1056 (11th Cir. 2005), and *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); see also *Andrx Pharm. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y.2003).

<sup>105</sup> *Hartford-Empire v. United States*, 323 U.S. 386, 432 (1945); see also 35 U.S.C. § 271(d) (2000).

No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

*Id.*

<sup>106</sup> See, e.g., *Kobe v. Dempsey Pump Co.*, 198 F.2d 416 (10th Cir. 1952); Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV.

Regarding unilateral conduct, even courts have found patent acquisition and non-use to be unlawful when done by a firm with market power for the purpose of protecting a monopoly or other anticompetitive purposes.<sup>107</sup> For example, in *Kobe v. Dempsey Pump Co.*, the court found that a company which held numerous patents on hydraulic pumps used in pumping oil from wells violated antitrust law because for several years the company actively purchased every major patent for hydraulic pumps with the purpose and effect of protecting its monopoly.<sup>108</sup> Also, in *Bloch v. SmithKline*, the court refused to grant the defendant summary judgment on an antitrust claim which alleged that the defendant purchased an exclusive license for the sole purpose of suppressing it because the licensed product, if developed, would compete with one of the defendant's existing products.<sup>109</sup> Other cases have upheld similar allegations as cognizable claims: defendants have obtained exclusive rights from inventors, rivals, collaborators, and even employees for the purpose of suppressing competition.<sup>110</sup> Additionally, several commentators have opined that where anticompetitive purpose or effect are found, unilateral acquisition by a firm with market power should be unlawful.<sup>111</sup> The authors of *Antitrust Law* take a

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J.L. & TECH. 389 (2002); *United States v. Parker-Rust-Proof Co.*, 61 F. Supp. 805 (E.D. Mich. 1945); Cohen & Burke, *supra* note 1.

<sup>107</sup> *Kobe*, 198 F.2d at 416; *Bloch v. SmithKline Beckman Corp.*, No. 82-510, 1988 U.S. Dist. LEXIS 12397, at \*1 (E.D. Pa. Nov. 1, 1988).

<sup>108</sup> *Kobe*, 198 F.2d at 423.

<sup>109</sup> *Bloch*, 1988 U.S. Dist. LEXIS 12397, at \*26.

<sup>110</sup> See *Parker-Rust-Proof Co.*, 61 F. Supp. at 811 (acquisition of an exclusive license from significant rival for purpose of eliminating competition violated Section 1 and Section 2 of the Sherman Act); *Magic Chef v. Rockwell Int'l*, 561 F. Supp. 732, 734 (N.D. Ill. 1983) (Plaintiff, a former licensee of a product developed by a joint venture in which the defendant was a participant, alleged that the defendant, via several acts, drove the joint venture and all other participants into bankruptcy for purpose of buying the patents rights in an auction, using the license exclusively, and refusing to license it. The court denied the defendants motion to dismiss.); see also *McDonald v. Johnson & Johnson*, 722 F.2d 1370, 1373-75 (8th Cir. 1983); *Turner v. Johnson & Johnson*, 549 F. Supp. 807, 809 (D. Mass. 1982) (two cases involving purchases by the defendant, Johnson & Johnson, of smaller companies, where the plaintiffs were former employees of the purchased companies who alleged that as part of the purchase agreement, the defendant agreed to develop and market a certain product of the former company, but that after the purchase intentionally suppressed the product because it competed with Defendant's product(s). In both cases, although the court found suppression had occurred, summary judgment was granted for the defendant on grounds of lack of standing); *Alling v. Universal Mfg. Corp.*, 7 Cal. Rptr. 2d 718, 728-29 (Cal. Ct. App. 1992) (The plaintiff invented and licensed an electronic lamp ballast to Defendant, which was capable of dimming florescent lights when exposed to increasing levels of natural light. According to the plaintiff, in exchange for the license the defendant promised to use its best efforts to produce and market the device. After a few years, the product was still not developed and the plaintiff sued alleging that the defendant was suppressing the product because it would compete with the defendant's magnetic ballasts. The court dismissed the antitrust claims on standing grounds.); see also *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (9th Cir. 1981) (finding that the patent acquisition involved did not violate Section 2, the court noted, "[s]urely, § 2 violation will have occurred where, for example, the dominant competitor in a market acquires a patent covering a substantial share of the same market that he knows when added to his existing share will afford him monopoly power").

<sup>111</sup> See VON KALINOWSKI, *supra* note 71, at §§ 73.01, 73.02(2)(a); JAY DRATLER, JR., LICENSING OF INTELLECTUAL PROPERTY § 8.05(1)(b) (1994); Saunders, *supra* note 106, at 433-34; Cohen & Burke, *supra* note 1; Yee Wah Chin, *Unilateral Technology Suppression: Appropriate Antitrust and*

particularly strong position: An acquisition of exclusive rights in “related” patents by a firm with market power ought to be unlawful by itself without having to provide evidence of non-use.<sup>112</sup> Finally, a review of non-patent cases suggests that, even in the absence of intellectual property rights, the acquisition of an essential or valuable resource from a rival, for anticompetitive purposes, could potentially violate antitrust law.<sup>113</sup>

Joint firm acquisition and non-use of patents has also been condemned under antitrust law.<sup>114</sup> These issues have been raised most frequently in cases involving “patent pools” and cross-licensing agreements between firms.<sup>115</sup> When these

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*Patent Law Remedies*, 66 ANTITRUST L.J. 441 (1998); John Flynn, *Antitrust Policy, Innovation Efficiencies, and the Suppression of Technology*, 66 ANTITRUST L.J. 487, n.57 (1998).

<sup>112</sup> 3 AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 707a. As defined, a related patent is: any patented product or process that is a substitute for or an improvement upon the monopolized product, a component thereof, or the process used in producing it. A related patent may cover the competitive equivalent of the product, component, or process of the monopolist; it may be inferior; it may be an improvement patent ‘subserving’ to the monopolist’s basic patent; or it may cover a superior non-infringing product or process.

*Id.*

By acquiring a patent, the monopolist might prevent present or future competition challenging its monopoly. The clearest case would be the acquisition of an equivalent patent covering the only known economic alternative to the monopolist’s product or process. Such an acquisition forecloses potential competition by rivals who might otherwise have access to that patent. Even the acquisition of one out of several equivalent patents might have exclusionary effects. The acquired patent might—with further advances in the art—turn out to have been the most promising. As a practical matter, it is not worthwhile to try to make that kind of determination or even to try to determine which patents are equivalent. Similarly, the acquisition of an inferior patent would have anticompetitive effects whenever third parties had developed, subsequently developed, or subsequently would have developed improvements that make it equal or superior to the monopolist’s patent. Again, it would be difficult in practice to determine whether that would be the result or, indeed, whether the patent was “inferior” to start with. The acquisition of an exclusive license in a patent covering an improvement to the monopolist’s basic patent might enable the monopolist to perpetuate its monopoly beyond the period of the basic patent. The acquisition facilitates protection not only for the original life of the basic patent, but also for the life of the improvement patent. And even if any particular improvement patent is relatively unimportant in itself, there are the anticompetitive dangers of accumulation.

*Id.* ¶ 707b; see also *id.* ¶¶ 708e, 803d1; HERBERT HOVENKAMP, MARK JANIS, AND MARK LEMLEY, IP AND ANTITRUST, AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW §14.4 (2002) (agreeing with ANTITRUST LAW).

<sup>113</sup> “Predatory hiring” cases are a good example. In these sparse cases, it has been alleged that the defendant company hired one or more of its rivals’ essential employees for the purpose of harming its competitors, rather than for their skill. Although no court has yet to rule on the issue, a few courts have stated that, if proven, such assertions may violate the Sherman Act. See *Taylor Publ’g v. Jostens*, 216 F.3d 465, 480 (5th Cir. 2000); *Midwest Radio Co. v. Forum Pub. Co.*, 942 F.2d 1294, 1297–98 (8th Cir. 1991); *Universal Analytics v. MacNeal-Schwendler Corp.*, 914 F.2d 1256, 1258 (9th Cir. 1990); *Wichita Clinic v. Columbia/HCA Healthcare Corp.*, 45 F. Supp. 2d 1164, 1195 (D. Kan. 1999).

<sup>114</sup> *Kobe v. Dempsey Pump Co.*, 198 F.2d 416, 423 (10th Cir. 1952).

<sup>115</sup> A “patent pool” is the sharing, or “pooling” by two or more firms of exclusive rights granted under each other’s patents. See AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 2043. “Cross licensing”

agreements have an anticompetitive purpose and effect, antitrust liability may result.<sup>116</sup>

Thus, for example, in *Kobe*, two firms created a patent pool with numerous acquired patents for hydraulic pumps.<sup>117</sup> Because the court found that the “purpose of the pool was to acquire patents relating to hydraulic pumps and to do everything reasonably within its power to ‘build up and maintain its patent monopoly,’” the court held the arrangement to be unlawful.<sup>118</sup> In *United States v. Singer Manufacturing*, defendant Singer was the sole U.S. manufacturer of household zigzag sewing machines.<sup>119</sup> Singer entered into an agreement with two European manufacturers of sewing machines, involving cross-licensing and the transfer of a patent, purportedly to obviate the need to litigate the validity and infringement of a dubious patent.<sup>120</sup> Because the court found “a common purpose to suppress the Japanese machine competition in the United States through the use of the patent,” it held that the agreement was an unreasonable restraint under the Sherman Act.<sup>121</sup> Similarly, in *Zenith Radio Corp. v. Hazeltine*, the Supreme Court held that a patent pool violated section 1 of the Sherman Act because the pool’s “chief purpose” was to exclude competition and it was effective in doing so.<sup>122</sup>

### III. ANTITRUST ANALYSIS OF THE TANOX-NOVARTIS-GENENTECH COLLABORATION

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is a very common way in which pooling is done, where each participant in the pool grants a cross license to each other member. *Id.* Patent pools come in many forms, and range from simple cross-licensing agreements to creation of separate “holding” companies to which the relevant patents are assigned.

<sup>116</sup> *Kobe*, 198 F.2d at 423.

<sup>117</sup> *Id.* at 419–20.

<sup>118</sup> *Id.* Defendant Kobe was actually a holding company created by former competitors, which is why both Section 1 and Section 2 liability were imposed. Key to the decision was the finding that for approximately 15 years, the firms actively acquired all material patents relating to hydraulic pumps, while continuing to manufacture the same product under the original patent. The acquired patents were neither used nor improved upon.

<sup>119</sup> *United States v. Singer Mfg.*, 374 U.S. 174, 176 (1963).

<sup>120</sup> *Id.* at 180–84.

<sup>121</sup> *Id.* at 195.

<sup>122</sup> *Zenith Radio Corp. v. Hazeltine*, 395 U.S. 100 (1969). *Hazeltine* involved, *inter alia*, several Canadian manufacturers of televisions and radios who had transferred patents to a holding company which refused licenses to any importer who did not manufacture in Canada (and comply with other rules). In holding that the pool, acting in conspiracy with American patent holders, violated section 1, the court found that “[t]he chief purpose of the pool was to protect the manufacturing members and licensees from competition by American and other foreign companies seeking to export their products into Canada.” *Id.* at 115. The pool aggressively acted to prevent importation by U.S. firms, policing the markets, sent warning notices to distributors, dealers, and consumers, and initiated infringement suits and threats. *Id.*; see also *Honeywell v. Sperry Rand Corp.*, 1974-1 Trade Cases ¶ 74,874 (E.D. Minn. 1973) (condemning exclusive cross-licensing arrangements between leading tabulating machine maker and leading data processing machine maker which allegedly kept other firms out of the market); *U.S. v. Kelsey-Hayes Wheel Co.*, 1955 Trade Cases ¶ 68,093 (E.D. Mich. 1955) (consent decree prohibiting manufacturers of metal wheels from, *inter alia*, jointly acquiring patents, entering into cross-licensing agreements where licensing outside of the pool was prohibited, or entering into non-compete agreements with competitors); *United States v. Gen. Instrument Corp.*, 87 F. Supp. 157 (D.N.J. 1949) (challenging a settlement which resulted in an agreement between firms to cross-license and aggressively exclude rivals).

In this section, I will discuss the two primary competitive concerns raised by the anti-IgE collaborative efforts between Tanox, Novartis, and Genentech: (1) whether the collaboration as a whole was anticompetitive; and (2) whether the prohibition against Tanox's independent development rights to CGP 56901 was an unreasonable restraint.

### *A. Assessment of the Collaboration As a Whole*

As previously mentioned, antitrust law views horizontal collaborations with a certain amount of apprehension, but acknowledges that they are often beneficial.<sup>123</sup> In assessing whether the collaboration as a whole is anticompetitive, courts and enforcement agencies generally focus on the nature of the collaboration, its purpose, and its effect or potential effect.<sup>124</sup>

#### *1. Nature of the Collaboration*

Because certain agreements are more likely than others to have harmful effects, the nature of the collaboration is pertinent to whether it may be anticompetitive. Thus, antitrust law regards production collaborations, marketing collaborations, buying collaborations, standard setting collaborations, and R&D collaborations somewhat differently.<sup>125</sup> Generally, R&D collaborations have been viewed favorably and encouraged by both federal legislation and enforcement agencies.<sup>126</sup> Nevertheless, it has been acknowledged that these collaborations may be anticompetitive if they stifle the pace of R&D efforts or lower the quality of products.<sup>127</sup>

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<sup>123</sup> Marc G. Schildkraut, *Payment-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1051 (2004).

<sup>124</sup> See, e.g., *Broad. Music Inc. v. Columbia Broad. Sys.*, 441 U.S. 1 (1979); FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.3, 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>125</sup> FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.31(a), 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>; AREEDA & HOVENKAMP, ANTITRUST LAW ¶¶ 2134–37.

<sup>126</sup> National Cooperative Research and Production Cooperative Act, 15 U.S.C. §§ 4301–06 (2000) (enacted in 1984, amended in 1993, and designed to encourage efficient, beneficial joint research). If a collaboration meets the statutory requirements, it *must* be evaluated under the rule of reason. 15 U.S.C. § 4302 (2000). Moreover, if the collaboration files proper notice with the Department of Justice, subsequent antitrust damages will be limited to single rather than treble damages. 15 U.S.C. § 4303 (2000); see also FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.31(a), 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm> (stating that research and development collaborations are usually pro-competitive and thereby evaluated by the agencies under the rule of reason).

<sup>127</sup> FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.31(a), 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.



Although benign on its face, the facts surrounding the creation, structure, and respective roles of the participants in the Tanox-Novartis-Genentech collaboration, along with issues pertaining to the collaboration's purpose and effect, raise considerable concerns regarding its effect on innovation of anti-IgE antibody products. In particular, Tanox's limited role in the collaboration and the prohibition on its independent development of CGP 56901, raise concerns about Tanox's ability and incentives to compete with the collaboration and its other members.<sup>128</sup> Unlike Novartis and Genentech, Tanox is a small company, which, at the time the collaboration was formed, had limited financing, few prospects for successful development and commercialization (apart from XOLAIR and CGP 56901), and continues to be heavily dependent on the success of XOLAIR for its existence and profitability.<sup>129</sup>

## 2. Purpose of the Collaboration

Although not conclusive, the underlying purpose behind any conduct may be relevant in determining its likely anticompetitive effect.<sup>130</sup> As applied to the Tanox-Novartis-Genentech collaboration, the purported purpose was to settle patent disputes and jointly develop anti-IgE antibody products.<sup>131</sup> However, despite this seemingly benign (and potentially beneficial) purpose, there are considerable factors that insinuate an anticompetitive purpose.

Tanox was the first of the collaborators to develop and patent anti-IgE antibodies.<sup>132</sup> Subsequently, both the Tanox-Novartis collaboration and Genentech each developed two anti-IgE antibodies separately.<sup>133</sup> Prior to the Agreements, Genentech and Tanox twice attempted to reach an agreement (and litigated for two years) before a collaboration between Tanox and Genentech did occur—as an essential condition for the settlement of all litigation.<sup>134</sup> The context in which the collaboration arose not only calls into question whether it was sincerely desired by all parties, but also, whether settlement of the patent dispute via establishment of the collaboration was on the whole pro-competitive.

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<sup>128</sup> Annual Report, *supra* note 11, at 6–7.

<sup>129</sup> See Annual Report, *supra* note 11, at 20–21.

Our results of operations and future prospects are highly dependent on increasing the sales of our only commercial product, XOLAIR. Our revenues in 2004 consisted largely of revenue from product sales of XOLAIR, and we expect that revenues from sales of XOLAIR will constitute a larger percentage of our revenue in the next several years. . . Under the terms of our collaboration agreements, Novartis and Genentech are generally responsible for conducting clinical trials on, obtaining regulatory approval for, and manufacturing, marketing and distributing XOLAIR. Our ability to profit from the products covered by our collaboration agreements with Genentech and Novartis depends in large part on their performance.

*Id.*

<sup>130</sup> *Cf.* United States v. United States Gypsum Co., 438 U.S. 422, 436, n.21 (1978).

<sup>131</sup> Annual Report, *supra* note 11, at 6–7.

<sup>132</sup> *Id.* at 3.

<sup>133</sup> *Id.* at 4.

<sup>134</sup> *Id.* at 6.

The structure of the collaboration, and particularly the participants' respective roles, is also indicative of an anticompetitive purpose. As mentioned, Tanox had a very limited role in the collaboration—essentially licensing its patents and receiving considerable payments.<sup>135</sup> Tanox did not share in the cost of development of the drug, and only shared in manufacturing and commercialization costs if it decided to exercise those rights (which were limited in themselves to Asia primarily).<sup>136</sup> Although it is possible that Tanox provided necessary knowledge and expertise to the collaboration, it is unlikely given the facts.<sup>137</sup>

When considered in total, the manner in which the collaboration arose, the respective roles of the participants, and the significance of the restraint against independent development rights (which Novartis and Genentech fought hard to enforce) raises serious doubts regarding the collaboration as an efficiency enhancing effort to develop and commercialize a new drug. Rather, it seems more like a clever means of stifling competition via patent acquisition and non-use.

### 3. *Effect of the Collaboration*

To fully assess the effects of the collaboration, a proper analysis necessitates an examination of both the adverse effects and the pro-competitive justifications. Regarding the Tanox-Novartis-Genentech collaboration, there are two principal anticompetitive effects: (1) a decrease in competition for the development of anti-IgE antibody products and (2) the shelving of a particular competing antibody, which showed promise in clinical trials. There are two pro-competitive justifications as well: (1) substantial efficiencies due to sharing of information, expertise, and costs and (2) that “but for” the collaboration, XOLAIR may not have been developed.

#### a. *Anticompetitive Effects*

Addressing the first potential anticompetitive effect, the collaboration indisputably decreased competition in the development of anti-IgE products.<sup>138</sup> However, this does not amount to an *ipso facto* determination that the collaboration was wholly anticompetitive. As mentioned, under modern antitrust doctrine, the critical assessment in ascertaining whether conduct is anticompetitive or not is

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<sup>135</sup> *Id.* at 6–7.

<sup>136</sup> *Id.* at 6–7.

<sup>137</sup> *Id.* at 6–7. XOLAIR is Genentech's antibody, and thus Tanox probably has no particular expertise or knowledge regarding its development. *Id.* Moreover, Novartis and Genentech have a great deal more experience in developing and commercializing drugs. *See* Genentech's Motion for Summary Judgment Regarding Contract Issues at 5, *Genentech, Inc. v. Tanox, Inc.*, No. 99-2060 (N.D. Cal. Feb. 28, 2001). The fact that XOLAIR was developed successfully despite Tanox being excluded from meetings of the Steering Committee and denied access to information on the drug, would tend to contravene finding that Tanox was an integral part of the collaboration. *See* Genentech's Opposition to Tanox's Motion for Preliminary Injunction at 1, *Genentech*, No. 99-2060 (Sept. 10, 2001).

<sup>138</sup> Annual Report, *supra* note 11, at 6–7.

whether the conduct harms *consumers*.<sup>139</sup> Depending upon the competitiveness of the market, a decrease in competition may have no effect on consumers.<sup>140</sup> Accordingly, to ascertain the competitive effect of the Tanox-Novartis-Genentech collaboration requires a preliminary evaluation of the industry, i.e., market concentration, entry barriers, potential entrants, viable substitutes (if any), and in particular, the existence and extent of market power.<sup>141</sup> Unless the collaboration was a sham or otherwise created for anticompetitive purposes, then absent evidence of market power, the collaboration would be deemed lawful with no additional evaluation of the collaboration and its effects necessary.<sup>142</sup>

Regarding the second potential anticompetitive harm, the stifling of a promising, potentially competing drug, this concern is also insufficient by itself to condemn the collaboration outright. First, assuming that the collaboration was established for a valid purpose and the collaborators genuinely believed that XOLAIR was the better drug to develop,<sup>143</sup> it would be imprudent to attach antitrust liability *ex post facto*

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<sup>139</sup> See FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 2.2, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), *available at* <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>140</sup> In fact, it has been asserted that decreased competition caused by a joint venture of former competitors may even *benefit* consumers in the long run. See 13 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2100 (2004). Under this theory, the promised benefits of increased innovation resulting from a collaboration of former competitors may outweigh even an immediate short term consumer loss (from coordination of output or increase in prices). *Id.* Moreover, it is important to remember that the collaboration was limited in scope to the four antibodies that were identified in the Outline of Terms, which were XOLAIR, E26, CGP 56901, and CGP 51901. Outline of Terms attached to Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment § 1, *Genentech*, No. 99-2060 (Feb. 28, 2001). The parties were free to independently develop *other* drugs which would compete with the collaboration. *Id.* This is clearly relevant for assessing the competitive effect of the collaboration and the prohibition against independent development.

<sup>141</sup> *United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 391–94 (1956). In this case, the relevant market would probably be the “innovation market” for the research and development of anti-IgE antibody products. See U.S. DEP'T OF JUSTICE & FTC, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 3.2.3 (1995) (expressly recognizing the existence of “innovation markets.”).

If a licensing arrangement may adversely affect competition to develop new or improved goods or processes, the Agencies will analyze such an impact either as a separate competitive effect in relevant goods or technology markets, or as a competitive effect in a separate innovation market. . . . An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development. The close substitutes are research and development efforts, technologies, and goods that significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to retard the pace of research and development.

*Id.*

<sup>142</sup> See FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), *available at* <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>. This is assuming, of course, that it is determined that the collaboration is not merely a farce to stifle competition, fix prices, or decrease output, in which case it would be *per se* illegal, regardless of any anticompetitive effects. *Id.*

<sup>143</sup> That is, at the time the decision was made, Tanox, Novartis, and Genentech believed XOLAIR would be a better choice to develop and commercialize than the other three anti-IgE

even assuming that it is later determined that CGP5601 was a better drug to develop and commercialize or that both drugs could have been developed. If participants of a joint venture had to fear antitrust liability for engaging in conduct for other than anticompetitive purposes that subsequently resulted in harm to competition, potentially beneficial collaborations would likely be deterred.<sup>144</sup> Second, because patent law does not require a patent holder to use or share his patents, then absent evidence that the purpose or nature of the collaboration is anticompetitive, assessing antitrust liability against a collaboration for non-use of a patent would be inconsistent with the Patent Act.<sup>145</sup> Consequently, condemning a collaboration outright based on the joint decision not to develop a single drug, without considering the nature and purpose of the collaboration, pro-competitive justifications, or some market analysis, would not only conflict with patent law, but would be bad policy.<sup>146</sup>

*b. Pro-Competitive Justifications*

The potential pro-competitive justifications, although plausible, suffer from a lack of factual support. First, Tanox's limited role in the collaboration, its exclusion from Steering Committee meetings, and its lack of access to confidential information on XOLAIR, contravenes the assertion that the tripartite collaboration was necessary (by creating substantial efficiencies via the sharing of knowledge and expertise). Second, any argument that development of XOLAIR could not have occurred but for the collaboration is spurious. This is not a case where firms cooperated for the purpose of making a new discovery or invention. Rather, the collaboration involved developing and commercializing antibody products from antibodies *which were already identified and synthesized*.<sup>147</sup> Viewed in this manner, the collaboration could just as readily be characterized as a production joint venture than as an R&D joint

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antibodies that were "owned" by the collaboration for valid business reasons, e.g., it would be less costly to develop or take through clinical trials, health reasons, or scientific reasons, and that it would not be cost efficient or practicable to develop both drugs. Outline of Terms attached to Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment § 3, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>144</sup> If the members of the joint venture or the collaboration had market power, antitrust liability for conduct engaged in for other than anticompetitive purposes that resulted in *foreseeable anticompetitive effects* could arguably be the basis of sound policy.

<sup>145</sup> Of course, there are many who disagree with the U.S. rule granting the patent holder an unfettered right to his patent, and not permitting forced licensing regardless of the social benefit of the invention.

<sup>146</sup> See FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), *available at* <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>. Although in this case consumers may in fact be harmed by the stifling of a promising drug, a rule that would condemn the collaboration on this fact alone is probably overbroad. Imagine, for instance, that this same collaboration invented a new life saving drug, which due to the substantial cost and risks, no firm on its own would have attempted to create and develop.

<sup>147</sup> See FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.31(a), 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), *available at* <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

venture.<sup>148</sup> Moreover, XOLAIR was Genentech's antibody, which it brought to the collaboration.<sup>149</sup> Genentech is a large pharmaceutical company with substantial resources and expertise in developing and commercializing drugs—which is one reason why Tanox initially sought to collaborate with Genentech in 1989.<sup>150</sup> Consequently, it is not likely that Genentech needed Tanox to develop XOLAIR.

### *B. Assessment of the Restraint Against Independent Development*

As with the analysis of the Tanox-Novartis-Genentech collaboration as a whole, in evaluating the reasonableness of the restriction against Tanox's independent development rights to CGP 56901, the nature of the restraint, its purpose, and its effects must be examined. However, in assessing the reasonableness of the restraint, an additional step is required. If it is determined that the restraint is not per se illegal, and a plausible, legally cognizable pro-competitive justification for the restraint has been proffered, an analysis regarding whether the restraint was reasonably necessary to achieve such a pro-competitive benefit should be made.

#### *1. Nature of the Restraint*

A restraint which prohibits participants of a collaboration from engaging in any activity that competes with the collaboration is tantamount to an agreement not to compete or a market allocation.<sup>151</sup> Generally such agreements are held to be per se illegal because they have the likely effect of raising prices or decreasing output.<sup>152</sup> However, courts and enforcement agencies have recognized that in the context of a joint venture, a restraint of the type that would normally be per se illegal may have significant pro-competitive effects, e.g., permitting the creation a new product, and thus may avoid per se treatment if reasonably necessary to achieve the pro-competitive effects.<sup>153</sup> "To be reasonably necessary, the restraint must not only

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<sup>148</sup> That is not to say that obtaining FDA approval, developing a drug, producing the drug, and commercializing it are easy tasks. These endeavors require a tremendous amount of resources, which is a classic justification for granting a patent on drugs. In this case, the Steering Committee selected XOLAIR only after the Phase II clinical trials of the antibodies were completed. A substantial amount of resources were still required prior to obtaining approval for XOLAIR and commercializing the drug. Outline of Terms attached to Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment § 1, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>149</sup> Outline of Terms attached to Declaration of Nancy Chang In Support Of Defendant Tanox's Motion For Summary Judgment § 1, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>150</sup> Defendant Tanox Inc.'s Memorandum in Support of its Motion for Preliminary Injunction and Notice of Motion at 5, *Genentech*, No. 99-2060 (Aug. 15, 2001).

<sup>151</sup> See *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972); FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>152</sup> See, e.g., *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 48 (1990); *United States v. Topco Assoc.*, 405 U.S. 596, 608 (1972); FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>153</sup> *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 113 (1984); *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 188 (7th Cir. 1985); *Rothery Storage & Van v. Atlas Van Lines*, 792 F.2d

promote the legitimate objective but must also do so significantly better than the available less restrictive alternatives.”<sup>154</sup> Nevertheless, even in the context of a beneficial, pro-competitive joint venture, restraints on non-venture activities are generally viewed as likely anticompetitive and not reasonably necessary to the venture.<sup>155</sup>

Based on the pertinent facts in this case, the parties might proffer the following three justifications for the restraint against independent development: (1) the restraint prevented the collaborators from “free riding” off knowledge and information of the collaboration, for their private use and exploitation; (2) “but for” the restraint, no collaboration would have been agreed to; and (3) independent development of CGP 56901 risked potential non-competitive harm to the success of XOLAIR.

Regarding “free riding,” Novartis and Genentech have asserted in pleadings that one reason why they refused to grant Tanox independent development rights was because they did not believe it was fair to allow Tanox to free ride off of their expertise and knowledge in the development of XOLAIR for its private use in developing CGP 56901.<sup>156</sup> Although free riding considerations have been accepted as

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210, 229 (D.C. Cir. 1986); *see also* FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), *available at* <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm> (“Before accepting a claim that an agreement is reasonably necessary to achieve procompetitive benefits from an integration of economic activity, the Agencies undertake a limited factual inquiry to evaluate the claim.”); 11 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1912c (2004) (“An ancillary restraint is one that is reasonably related to a joint venture or transaction that, at least on initial examination, promises to increase output, reduce costs, improve product quality, or otherwise benefit consumers.”).

It is important to recall that if a restraint is found to be per se illegal, it will be condemned irrespective of market power—and without any analysis of the market. *See* FTC v. Ind. Fed’n of Dentists, 476 U.S. 447, 458 (1986). All other restraints will require some analysis, although depending on the nature and effect of the restraint, a full blown rule of reason may not be required. *See id.* at 458; Polygram Holding Inc. v. FTC, 416 F.3d 29, 33 (D.C. Cir. 2005); Law v. Nat’l Collegiate Athletic Ass’n, 134 F.3d 1010, 1016 (10th Cir. 1998).

<sup>154</sup> 7 PHILLIP E. AREEDA, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1505 (2004).

An agreement may be “reasonably necessary” without being essential. However, if the participants could achieve an equivalent or comparable efficiency-enhancing integration through practical, significantly less restrictive means, then the Agencies conclude that the agreement is not reasonably necessary. In making this assessment, except in unusual circumstances, the Agencies consider whether practical, significantly less restrictive means were reasonably available when the agreement was entered into, but do not search for a theoretically less restrictive alternative that was not practical given the business realities.

FTC & U.S. Dep’t of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), *available at* <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>155</sup> 13 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2131c (2004); Polygram Holding, Inc. v. FTC, 416 F.3d 29, 38 (D.C. Cir. 2005) (rejecting free riding justification for non-venture restraints). *But see* SCFC ILC, Inc. v. Visa U.S.A., Inc., 36 F.3d 958, 972 (10th Cir. 1994).

<sup>156</sup> *See* Genentech’s Motion for Summary Judgment Regarding Contract Issues at 5, Genentech, Inc. v. Tanox, Inc., No. 99-2060 (N.D. Cal. Feb. 28, 2001).

a sufficient justification for certain restraints in a joint venture,<sup>157</sup> and may well be appropriate in the context of an R&D collaboration, as applied to the Tanox-Novartis-Genentech collaboration, it does not appear to be particularly compelling. First, the facts do not manifest significant free riding concerns. Although CGP 56901 was developed and taken to Phase II clinical trials by the Tanox-Novartis collaboration, it was created from Tanox's research and discovery.<sup>158</sup> The tripartite collaboration chose to develop XOLAIR, an asthma drug, instead of CGP 56901, which was designed to treat peanut allergies.<sup>159</sup> Thus, absent evidence revealing that Tanox unlawfully used confidential information or trade secrets, free riding concerns do not appear to be exceptional.<sup>160</sup> Second, an outright prohibition of independent development seems excessive, that is, not reasonably necessary to prevent any justifiable free riding concerns. Other less restrictive means were available, such as a confidentiality agreement.<sup>161</sup>

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Tanox would be free-riding off Genentech by asking Genentech to carry the significant costs of research and development of Tanox's molecule while giving Genentech potentially no rights in that molecule in return. Since Tanox was far less experienced than Genentech in regulatory proceedings, manufacturing, and marketing, Genentech also—rightly—feared that Tanox would be taking unfair advantage of Genentech's expertise in those areas in furtherance of Tanox's scheme to develop a product that Tanox then would use to compete against the contemplated collaboration.

*Id.*

<sup>157</sup> See, e.g., SCFC ILC, Inc. v. Visa U.S.A., Inc., 36 F.3d 958, 970 (10th Cir. 1994); Rothery Storage & Van v. Atlas Van Lines, 792 F.2d 210, 212–13 (D.C. Cir. 1986); 13 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2131c (2004).

<sup>158</sup> Recall that Tanox was the first of the collaborators to develop anti-IgE antibodies, and sought collaborations primarily because it needed financing and assistance with development and commercialization. See Annual Report, *supra* note 11, at 3, 6–7. Thus in all likelihood, the inventiveness behind CGP 56901 was a result of Tanox's research.

<sup>159</sup> See Genentech's Motion for Summary Judgment Regarding Contract Issues at 10, *Genentech*, No. 99-2060 (Feb. 28, 2001).

<sup>160</sup> Absent concerns of unlawful use of confidential information or trade secrets, defining a collaborator's use of any knowledge, skill, or experience obtained in a collaboration as "free riding" would be perverse. As defined, "free riding" would include experience and skills learned by an individual on the job, and could be used to defend broad non-compete restraints for ex-employees.

<sup>161</sup> In fact, in the Complaint, Novartis and Genentech did assert a claim that the Outline of Terms included a confidentiality agreement and that Tanox violated it by using confidential information in the development of CGP 56901, as well as misappropriation of trade secrets. See Complaint for Declaratory Relief, Breach of Contract, Breach of Implied Covenant of Good Faith and Fair Dealing, Unfair Competition and Misappropriation of Trade Secrets ¶¶ 50–52, 77–79, *Genentech*, No. 99-2060 (Apr. 29, 1999). However, the court essentially dismissed this claim, finding that under the Outline of Terms, Tanox "... retained independent development rights under the D&L Agreement after signing the Outline of Terms" and that "... the Outline of Terms permits Tanox's use of confidential information in the process of developing rejected antibodies." Memorandum and Order at 2, *Genentech*, No. 99-2060 (Oct. 9, 2001). The fact that an arbitration panel subsequently decided that the scope and extent of Tanox's independent development rights did not extend to the development of CGP 56901, does not alter the finding that Tanox did not violate any confidentiality agreement in the Outline of Terms.

More pertinent for antitrust purposes: if Genentech and Novartis's primary claim against independent development was that it should be prevented because it was developed via using unlawful confidential information, know-how, and trade secrets, and could *prove* that, the case would be very different. But instead, from the very beginning Novartis and Genentech's chief argument was that Tanox was contractually prohibited from developing CGP 56901 for the very

The “but for” justification is essentially that the collaboration would not have occurred without the restraint because Novartis and Genentech would have never agreed to it.<sup>162</sup> While this may be true, it is not obvious whether this result would harm *consumers*. As previously noted, any claim that XOLAIR would not have been created “but for” the collaboration is disingenuous. Thus, because XOLAIR would have been created regardless, the only benefit of the collaboration for consumers would be if it resulted in decreased prices, increased output, faster commercialization, or more expansive commercialization. Moreover, even if some or all of these benefits came to fruition, they would have to be weighed against the potential benefits of CGP 56901 being developed. That is, absent the collaboration, Tanox may have been able to help those with peanut allergies by developing CGP 56901 via obtaining sufficient financing to develop the drug on its own, entering into a different collaboration which actually developed the drug, or selling the patent rights to another firm that was able to develop it.<sup>163</sup> Accordingly, the “but for” justification is not especially compelling, since it is not evident that the “but for” scenario is any worse; and, in fact, it could have been better.

Finally, the “harm” justification for the restraint can be dismissed fairly easily. The crux of this argument appears to be that that Tanox’s independent development of CGP 56901 could adversely affect XOLAIR’s approval by the FDA because: (1) as a new, inexperienced company, Tanox may fail to obtain FDA approval for CGP 56901; and (2) similarities between XOLAIR and CGP 56901 may adversely affect FDA approval of XOLAIR.<sup>164</sup> Assuming this to be true, a prohibition on independent development does not appear to be “reasonably necessary” to preventing the harm. That is, other less restrictive means are available to protect the purported harm such as having Tanox compensate Genentech and/or Novartis for assisting it in obtaining FDA approval, or requiring that Tanox wait until XOLAIR obtains FDA approval before seeking approval for CGP 56901.<sup>165</sup>

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reason that it would compete with XOLAIR and that they would never have entered into the Agreements if Tanox were permitted to independently develop CGP 56901.

<sup>162</sup> See Genentech’s Motion for Summary Judgment Regarding Contract Issues at 2, *Genentech*, No. 99-2060 (Feb. 28, 2001) (“Why would Genentech and Novartis have agreed to a ‘collaboration’ that not only allows Tanox to undermine the collaborative market share but also jeopardizes the success of the collaboration altogether? They would not have, and they did not”).

<sup>163</sup> Of course, this assumes that CGP 56901 successfully treated peanut allergies, completed clinical trials, was approved by the FDA, and was developed and commercialized.

<sup>164</sup> Genentech’s Motion for Summary Judgment Regarding Contract Issues at 1, 6, *Genentech*, No. 99-2060 (Feb. 28, 2001).

Tanox has never undertaken any development like this before, and Tanox admits that any misstep in its unilateral development of the backup molecule [CGP 56901] could have profound effects on the approval and usage of E25 [XOLAIR] itself. . . . [I]f Tanox were to seek regulatory approval for its molecule at the same time as the contemplated collaboration [XOLAIR], any setbacks suffered by Tanox due to inferior research or Tanox’s pursuit of regulatory approval could have serious implications for the collaboration’s chosen molecule as well, given the two molecule’s similar activity.

*Id.*

<sup>165</sup> XOLAIR obtained FDA approval for the treatment of asthma in 2003. Letter from Sharon T. Risso, Acting Director, Center for Biological Evaluation and Research to Robert L. Garnick, Senior Vice President, Genentech, Inc. This occurred after the Outline of Terms, but before the final,



## 2. Purpose of the Restraint

As evinced throughout the record in the litigation, Novartis and Genentech's chief motive for prohibiting Tanox from developing CGP 56901, is the belief that it would compete with XOLAIR and moreover, that it would bestow an unfair windfall to Tanox:

Tanox has single-handedly attempted to develop the E25 backup-option molecule—a molecule that Tanox itself rejected in favor of E25—to compete with its collaborators Genentech and Novartis in the anti-IgE marketplace. By doing so, Tanox has breached both the plain language of the Outline of Terms and its underlying intent by appropriating for itself a molecule that belongs to the tripartite collaboration.

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Tanox could still take market share away from the collaboration if Tanox persisted in asserting “independent development rights” in a molecule that the collaboration had jointly developed. For even if Tanox sought FDA approval for different uses of the molecule than those intended for the collaboration's chosen molecule, doctors could still legitimately prescribe Tanox's drug “off label”—and potentially at lower cost—for the indications originally targeted by the collaboration.<sup>166</sup>

Considering that Genentech and Novartis incurred the cost and risk of developing and commercializing XOLAIR, while Tanox received substantial payment and royalties, this rationale is somewhat understandable. Tanox clearly benefited from the collaboration, and hence, if its development of CGP 56901 results in it profiting at the expense of its fellow collaborators, it is not surprising that the latter might perceive this as an unfair windfall.<sup>167</sup> However, antitrust law is not particularly concerned with profits or fairness among collaborators of a business

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Tripartite Collaboration Agreement was executed on February 25, 2004. XOLAIR has not yet obtained approval for the treatment of peanut allergies.

<sup>166</sup> Genentech's Motion for Summary Judgment Regarding Contract Issues at 1, 6–7, *Genentech*, No. 99-2060 (Feb. 28, 2001). Counsel for Genentech states:

What I would like is if we could get a protective order entered so that the documents could get produced. We can take some depositions, and we can come in here and either get an injunction or a declaration that that competing product been stopped. . . . Over a hundred million dollars have already been spent, and there will be huge expenses coming up for promotion when they launch the product, so we really need to not have a competing product in the market from our strategic partner.

Transcript of Proceedings at 9, *Genentech*, No. 99-2060 (June 12, 2000).

<sup>167</sup> This, of course, depends on one's views of the collaboration, and how it was formed: an efficient, consensual agreement to jointly develop a drug, sharing costs and know-how, or an acquiescence by Tanox after failed negotiations, various lawsuits, and years of litigation.

venture, but with competition and consumer welfare.<sup>168</sup> Accordingly, when evidence suggests that the primary motive behind a restraint imposed by a collaboration of former competitors is to hinder non-venture activities, then absent substantial pro-competitive justifications, such a purpose is generally deemed anticompetitive and condemned.

### 3. *Effect of the Restraint*

Although not typical, in this case the anticompetitive effect of the restraint is probably the same as the effect of the collaboration as a whole, and as a result, the two cannot be separated and treated independently. Here, the record evinces that the restraint regarding independent development rights was an integral component of the collaboration, and it is likely that the collaboration would not have been formed absent the restraint.<sup>169</sup> The importance of the restraint is obvious from the record: (1) Both the 1989 and 1993 collaboration attempts between Tanox and Genentech failed due in significant part to disagreement over Tanox's independent development rights and (2) many years and millions of dollars in litigation costs were spent disputing the scope and extent of Tanox's independent development rights.<sup>170</sup> Also, Genentech and Novartis have argued in pleadings that "but for" the restraint, they would not have agreed to the collaboration.<sup>171</sup> Given the facts surrounding the creation of the collaboration, the resources which Genentech and Novartis expended to enforce the restraint, and that XOLAIR would most likely have been developed absent the collaboration, I find substantial credence in this "but for" assertion. Consequently, for the most part, the same analysis used to evaluate the effects of the collaboration as a whole can be applied to assess the effects of the restraint, with similar indeterminate results.

## IV. CONCLUSION

This article has attempted to exemplify antitrust concerns that may arise in R&D collaborations among competitors. While such collaborations are often beneficial, permitting firms to share costs, information, and expertise, there is a clear potential for anticompetitive harm. Moreover, because these collaborations generally occur in innovative markets, the resulting harm via suppression of innovation is

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<sup>168</sup> See FTC & U.S. Dep't of Justice, Antitrust Guidelines for Collaboration Among Competitors § 3.2, 4 Trade Reg. Rep. (CCH) ¶¶ 13, 161 (2000), available at <http://www.ftc.gov/os/1999/10/jointventureguidelines.htm>.

<sup>169</sup> See Genentech's Motion for Summary Judgment Regarding Contract Issues at 4–5, *Genentech*, No. 99-2060 (Feb. 28, 2001); see also Transcript of Proceedings at 9, *Genentech*, No. 99-2060 (June 12, 2000).

<sup>170</sup> See Genentech's Motion for Summary Judgment Regarding Contract Issues at 4–5, *Genentech*, No. 99-2060 (Feb. 28, 2001); see also Transcript of Proceedings at 9, *Genentech*, No. 99-2060 (June 12, 2000).

<sup>171</sup> See Complaint for Declaratory Relief, Breach of Contract, Breach of Implied Covenant of Good Faith and Fair Dealing, Unfair Competition and Misappropriation of Trade Secrets ¶¶ 50–52, *Genentech*, No. 99-2060 (Apr. 29, 1999).

particularly acute. As illustrated by this article, courts should be particularly wary of restraints imposed on collaborators which impede their activities outside of the collaboration.

In the Tanox-Genentech-Novartis collaboration, the result indicated both a lessening of competition and the stifling of a drug which held promise for the treatment of peanut allergies. As discussed in Part III, the nature and purpose of both the collaboration as a whole and the restraint against independent development raise considerable anticompetitive concerns. As a result, although the actual effects of the collaboration and restraint are ambiguous, given the lack of discernable pro-competitive justifications and because the restraint “appears likely . . . to restrict competition,” neither a detailed market inquiry nor full rule of reason analysis should be required.<sup>172</sup> That is, based on the facts and aforementioned analysis, this case seems particularly appropriate for presumptively condemning the collaboration and the restraint against independent development under a so-called “quick look” or abbreviated rule of reason.<sup>173</sup>

That R&D collaborations might pose anticompetitive harm is not a radical or novel notion. Rather, as noted by commentators during the 1998 symposium on the suppression of technology, the real problem is assessing the likelihood and magnitude of anticompetitive harm, and devising an appropriate solution.<sup>174</sup> Unfortunately, given the lack of transparency of most collaborative activities and the unpredictable, non-linear nature of innovation in general, any such assessment is likely to be quite difficult to say the least. Unlike price fixing in a concentrated market of homogenous goods, harms imposed by R&D collaborations are generally not easily predicted by microeconomics, industrial organization, or applied game theory.

Nevertheless, how often R&D collaborations pose substantial anticompetitive effects are, of course, relevant to creating an optimal solution. Since both federal legislation and agency guidelines have expressed a policy of encouraging R&D collaborations, then unless anticompetitive concerns are seen as substantial, perhaps a case by case application of the current governing rules is the best way to address

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<sup>172</sup> A full blown market analysis is not required in a “quick look” or abbreviated rule of reason. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999); *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 460 (1986); *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 33 (D.C. Cir. 2005). Recall that market analysis is really just a proxy for assessing the competitive effects of a restraint. Thus, there is a strong argument that when facts demonstrate an anticompetitive nature and purpose, and defendants fail to offer plausible, cognizable pro-competitive justifications, that no market analysis is necessary.

<sup>173</sup> Of course, the parties have not had an opportunity to offer any justification. My evaluation was based solely on the public records in the most recent litigation—a contract dispute, where no pro-competitive justifications were required. Assuming that the parties could proffer valid, plausible, and legally cognizable pro-competitive justifications, a more thorough evaluation of the anticompetitive effects will be necessary—although a full, detailed market analysis may still not be required. *Cal. Dental Ass’n*, 526 U.S. at 770; *Ind. Fed’n of Dentists*, 476 U.S. at 460; *Polygram Holding*, 416 F.3d at 33. Moreover, it should be noted that absent the significant evidence of anticompetitive intent and that the restraint here was prima facie harmful (because it was imposed on non-venture activities), the outcome of an antitrust analysis would be much different. The limited scope of the collaborations (pertaining only to the four antibodies that were identified in the Outline of Terms), and a thorough market analysis would in all likelihood be much more supportive of finding the collaboration and restraint lawful.

<sup>174</sup> Cohen & Burke, *supra* note 1, at 424.

the problems. Still, given the growing importance of intellectual property in today's modern information society and the spiraling cost of health care including pharmaceutical drugs, perhaps a more tailored remedy is more suitable. For instance, the National Cooperative Research and Production Cooperative Act might be amended to provide additional guidance and safe harbors for R&D collaborations. Alternatively, another possibility would be to enact *sui generis* legislation, mandating different analysis for particularly troublesome areas such as pharmaceuticals, biotechnology, etc.

In the end, of course, the goal is to create a rule which provides greater certainty, encourages innovation, and deters anticompetitive conduct. How this balance is struck and whether a case by case or categorical approach is more appropriate, remains to be determined. However, as this article has demonstrated, given the potential for significant harm in R&D collaborations, it is my belief that unless and until a better solution is effectuated, antitrust law can and should be aggressively applied to examine such collaborations in order to protect consumers and competition.