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# Government Policy towards Innovation in the United States, Canada, and the European Union as Manifested in Patent, Copyright, and Competition Laws

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# GOVERNMENT POLICY TOWARDS INNOVATION IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION AS MANIFESTED IN PATENT, COPYRIGHT, AND COMPETITION LAWS

*Daniel J. Gifford\**

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## I. AN OVERVIEW

THE United States, Canada, the European Union, Japan and most industrialized nations have adopted patent, copyright and other intellectual property laws. A major or primary purpose of those laws is to foster innovation, including technological innovation. Industrial and technological innovation is generally perceived as a good because technological advances increase a society's productivity,<sup>1</sup> thus increasing its wealth and raising living standards. The major industrialized nations also possess competition laws, one of whose purposes is to preserve, foster and support competitive markets. These nations want to preserve competitive markets because competitive markets help to allocate available resources to their highest valued uses and generate increased productive efficiency, also helping to enrich society.<sup>2</sup> Since mid-century, the United States, Canada, Europe, Japan and other nations have been encouraging international trade, under the General Agreement on Tariffs and Trade (GATT) and the World Trade Organization (WTO), by progressively lowering their tariffs and eliminating other barriers to trade.<sup>3</sup> These efforts to promote freer trade help to allocate the world's resources more closely to their highest-valued uses, thereby increasing the aggregate wealth of the entire world.

That all of the major industrialized nations pursue policies that simultaneously support innovation, allocative efficiency and production efficiency are to be expected. These policies all aim at the enrichment of society. Since their underlying goals are similar, seeming conflicts in the applications of these various laws are capable of being readily resolved. Resort to the common element—welfare maximization—underlying them should aid immensely in construing their provisions and in selecting those interpretations which best harmonize apparent conflicts in their provisions.

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1. See, e.g., Joseph F. Brodley, *The Economic Goals of Antitrust: Efficiency, Consumer Welfare, and Technological Progress*, 62 N.Y.U. L. REV. 1020, 1026 (1987) ("studies have shown that over the forty-year period from the late 1920s to the late 1960s, at least half of the gain in United States output was due solely to technological and scientific progress.").

2. Daniel J. Gifford & Robert T. Kudrle, *Alternative Merger Standards and the Prospects for International Cooperation*, in *THE POLITICAL ECONOMY OF INTERNATIONAL TRADE LAW* 208, 210 (Daniel M. Kennedy & James D. Southwick eds., 2002); Daniel J. Gifford & Mitsuo Matsushita, *Antitrust or Competition Laws Viewed in a Trading Context: Harmony or Dissonance?*, in 2 *FAIR TRADE AND HARMONIZATION: PREREQUISITES FOR FREE TRADE?* 269, 277-79 (Jagdish N. Bhagwati & Robert E. Hudec eds., 1996).

3. See generally Daniel J. Gifford, *Antitrust and Trade Issues: Similarities, Differences, and Relationships*, 44 DEPAUL L. REV. 1049 (1995).

Despite the common welfare-advancing goals embodied in the intellectual property laws, competition laws and trade policies of these jurisdictions, every jurisdiction has deviated from those goals on occasion. In this paper, I examine several places where the innovation-fostering goals of the intellectual property laws have been undercut by legislatures or courts. The examples come from the United States, Canada, and the European Union. In many of these examples, I have been able to compare approaches taken to similar problems in different jurisdictions, thus providing a comparative-law aspect to this exploration of deviations from intellectual property goals.

The paper examines Canadian and United States approaches to the protection of patented pharmaceutical products in Part II. Then, in Part III, it explores the treatment of patented pharmaceutical products within the European Union in the context of differing national policies governing pricing and patent incentives. In Part IV it examines European and United States approaches to the patenting of DNA and proteins. In Part V, the paper explores judicial approaches to the protection of computer programs. Finally, in Part VI, the paper examines aspects of United States intellectual property misuse law and related issues of antitrust law as they relate to issues that are emerging in Europe and the United States. In each instance, the paper attempts to draw conclusions about the welfare effects of the policies examined.

## II. THE PATENT REGIME, PHARMACEUTICALS, PRICING, AND DIFFERING NATIONAL INTERESTS: THE CANADIAN AND U.S. APPROACHES TO PHARMACEUTICALS

Patent law is designed to stimulate inventive activity by conferring on inventors a period of exclusive rights in their inventions. In doing so, it incorporates several elements: the insight and skill of the inventor in identifying a societal need or want; the patent law itself that provides the means for the inventor to capture some of the invention's economic value; and the market as a means for directing the inventor's efforts to identify products that will meet social needs.<sup>4</sup> Pharmaceutical patents, like all patents, are designed to enable their holders to exploit the present market for society's long-term benefit. Because they cover products that affect health, this latent conflict (between the long and short terms) is more likely to be realized in government policies that give added weight to short-term interests. The attraction of the short-term to policy-makers,

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4. The patent system incorporates the advantages and disadvantages of the market. One of its deficiencies relating to the development of pharmaceutical products is that it stimulates the development of drugs useful in treating diseases common in developed nations and is not responsive to the needs of poorer societies. See Daniel J. Gifford, *How Do the Social Costs and Benefits of the Patent System Stack Up in Pharmaceuticals?* 11 J. INTEL. PROP. L. (forthcoming 2004).

however, may be partially offset by the existence of a domestic pharmaceutical industry.

These factors suggest that we should expect that legal regimes would differ in the respect they accord to pharmaceutical patents. Monopoly-level pharmaceutical prices may provide a stimulus to research and development, but the incentive-to-innovation rationale of the patent system is more easily accepted in nations with a domestic pharmaceutical industry. In those nations, the relationship between the patent system and the beneficial societal effects reflected in the generation of new medical products is reinforced when the public is aware of a thriving domestic industry that is dependent upon that system. It is true, of course, that innovative drugs are sold worldwide, so that the benefits of patent-stimulated research are widely available. But the additional factor that the system also supports a domestic industry sometimes makes the system more politically acceptable.

#### A. PATENT PROTECTION FOR PHARMACEUTICALS IN CANADA

Canada provides an interesting example of the two faces of intellectual property protection in the pharmaceutical industry. Canada is a highly developed nation, an economy integrated into the global economic system and even more heavily integrated with its trading partners in North America. It has a domestic pharmaceutical industry, albeit one that is largely composed of branches of foreign multinationals. These multinationals perform a significant amount of research activity in Canada. So, Canada experiences conflicting pressures. It would like to encourage the expansion of its domestic pharmaceutical industry, and it would also like to reduce the amounts that it pays for new pharmaceuticals.

Although Canada has always had an effective patent system, it historically has accorded a lesser level of protection for pharmaceutical products than for other subject matter.<sup>5</sup> In 1923, Parliament amended the Patent Act to provide for compulsory patent licenses for the production of drugs in Canada.<sup>6</sup> Under this legislated scheme, independent Canadian manufacturers would produce generic equivalents of patented drugs for a set royalty, usually four percent of sales.<sup>7</sup> Although this legislation was intended to foster competition among drug manufacturers that would

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5. On the Canadian treatment of patented pharmaceuticals, see generally Mary Atkinson, *Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada*, 11 PAC. RIM L. & POL'Y J. 181 (2002); Edward Hore, *A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry*, 55 FOOD & DRUG L.J. 373 (2000); Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L. REV. 215 (1999); Joel Lexchin, *After Compulsory Licensing: Coming Issues in Canadian Pharmaceutical Policy and Politics*, 40 HEALTH POL'Y 69 (1997).

6. Patent Act, S.C., ch.23, § 187 (1923) (Can.). See Lexchin, *supra* note 5, at 70; Atkinson, *supra* note 5, at 191.

7. Atkinson, *supra* note 5, at 191. See, e.g., *Novopharm Ltd. v. Jassen Pharm. N.V.*, 41 C.P.R. 3d 384, 389 (1992) (ordering 4% royalty).

drive down the prices of drugs, it achieved only limited success.<sup>8</sup> During the four and one-half decades following the amendment, only forty-nine compulsory licenses were sought and only twenty-two licenses were authorized by the Commissioner of Patents.<sup>9</sup> Canadian sources attribute the small number of licenses to the small size of the Canadian market being unable to sustain the numerous manufacturing facilities envisioned by the 1923 legislators.<sup>10</sup> To overcome this hurdle, the Patent Act was further amended in 1969 to extend compulsory licensing to imported drugs.<sup>11</sup> The authorities that claim that the Canadian market was too small to sustain generic drug manufacturing nevertheless report that the 1969 legislation helped to generate a domestic generic drug industry.<sup>12</sup>

Despite the apparent success of the revised compulsory licensing system, Parliament came to take the view that compulsory licensing discouraged research and development in Canada.<sup>13</sup> Accordingly, it enacted legislation in 1987 that deferred the entry of generic licensees for periods of seven to twenty years.<sup>14</sup> The patentees, however, although released from the competition of generics for at least seven years, were not free to price as they saw fit. During the period in which they were free from competition, the patentees' prices were made subject to control by the Patented Medicine Prices Review Board.<sup>15</sup> Despite the price control, however, research and development investment increased substantially, rising from 6.1% of sales in 1988 to 11.8% in 1995.<sup>16</sup>

The adoption of the North American Free Trade Agreement (NAFTA) required a number of changes in the Canadian patent law. Canada, like the United States, had previously observed a patent term of seventeen years from the date that a patent issued. NAFTA obligated its adherents to observe a patent term of twenty years from the date of filing.<sup>17</sup> It also placed severe limits on compulsory licensing.<sup>18</sup> In anticipation of NAFTA, the Parliament eliminated the compulsory-licensing system in 1993<sup>19</sup> and changed the patent term to twenty years from filing.<sup>20</sup> Later, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) imposed similar obligations.<sup>21</sup>

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8. See Lexchin, *supra* note 5, at 70.

9. *Id.*

10. *Id.*; see also *ICN Pharms., Inc. v. Canada (Patented Med. Review Bd.)*, 66 C.P.R. 3d 45, 48 (1996).

11. See Act to Amend the Patent Act, the Trade Marks Act & the Food & Drugs Act, R.S.C., ch. 49, § 1 (1968) (Can.).

12. Lexchin, *supra* note 5, at 104.

13. See *ICN Pharms., Inc.*, *supra* note 10, at 76.

14. Act to Amend the Patent Act, R.S.C., ch. 41 (1987) (Can.).

15. See *ICN Pharms., Inc.*, *supra* note 10, at 77.

16. Lexchin, *supra* note 5, at 71.

17. North American Free Trade Agreement, Dec. 17, 1992, art. 1709(12), 107 Stat. 2057, 32 I.L.M. 605.

18. *Id.* at art. 1709(10).

19. An Act to Amend the Patent Act, R.S.C., ch. 2, § 3 (1993) (Can.).

20. Patent Act, R.S.C., ch. P-4, § 39 (1997) (Can.).

21. Agreement on Trade Related Aspects of Intellectual Property Rights, art. 31 (limitations on compulsory licensing), art. 33 (patent term).

Both the United States and Canada have enacted legislation designed to ease the entry into the market by generic drug manufacturers. In the United States this legislation was combined with legislation to restore some of the patent term which is effectively taken from drug patentees by the lengthy period in which an already patented drug must await regulatory approval by the Food and Drug Administration (FDA) before it can be marketed.<sup>22</sup> In the Hatch-Waxman Act, adopted in 1984, Congress authorized patent term extensions to compensate for this waiting period.<sup>23</sup>

The Hatch-Waxman Act also eased the entry of generic manufacturers by allowing them, during the patent term, to use the patented drug to prepare their own submissions to the FDA.<sup>24</sup> They cannot submit their application for approval, however, until the patent term expires.<sup>25</sup> Perhaps even more important, the Act permits manufacturers of generic drugs to "piggy-back" on the research of the producer of the original, or "pioneer," drug and encourages them to challenge the patent and its coverage.<sup>26</sup> Under the Act, a generic drug manufacturer is permitted to file an abbreviated new drug application ("ANDA") which incorporates the data previously supplied by the pioneer-drug producer.<sup>27</sup> In addition, the generic manufacturer must certify information about the patent status of the pioneer drug: either that no patent has been issued; that the patent has expired; that the patent is invalid; or that the patent will not be infringed by the generic drug.<sup>28</sup> If the generic manufacturer certifies that the pioneer drug patent is invalid or will not be infringed ("paragraph IV certification"), the manufacturer of the pioneer drug is given forty-five days to bring a patent infringement suit.<sup>29</sup> The commencement of the patent action then triggers a stay on the approval of the generic for thirty months or until the court rules on the issues of patent validity and/or infringement.<sup>30</sup>

The Hatch-Waxman Act further incorporates incentives to attract generic manufacturers into the market. The first generic manufacturer to qualify under the paragraph IV certification provisions is rewarded with quasi-exclusivity: a 180-day period in which it shares the market only with the patentee, no other generics being permitted to enter during that pe-

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22. See 35 U.S.C. § 156 (2000).

23. The Hatch-Waxman Act permits extensions of the patent term equal to the time in which the patentee awaited final FDA approval plus one half of the post-patent-issuance time taken for running clinical tests. 35 U.S.C. § 156(c)(1)-(2) (2004). The period so calculated when added to the remaining patent term, however, cannot exceed fourteen years. *Id.* § 156(c)(3). And no extension can exceed five years. *Id.* § 156(g)(6)(A).

24. 35 U.S.C. § 271(e)(1) (2004). This provision overrules *Roche Prods., Inc. v. Bolar Pharms. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

25. 35 U.S.C. § 271(e)(2).

26. 21 U.S.C. § 355(j)(1), (2)(A)(i)-(iv)(2004).

27. *Id.*

28. 21 U.S.C. § 355(j)(2)(A)(vii).

29. *Id.* § 355(j)(5)(B)(iii).

30. *Id.*

riod.<sup>31</sup> Thus, the Hatch-Waxman Act carries provisions designed both to reinforce the incentives to innovate by restoring at least some of the patent term whose usefulness is lost to regulatory delays and to provide incentives to generics to challenge or avoid existing patents.

Canadian legislation, enacted in 1993, followed some, but not all, of the path marked out by the Hatch-Waxman Act. The Canadian legislation followed the part of the Hatch-Waxman Act that authorized generic producers, during the patent term, to use a patented drug to prepare their own regulatory submissions.<sup>32</sup> The Canadian regulations also followed several of the Hatch-Waxman procedures. Canadian regulations permit generic producers to “piggy-back” on the research supporting the pioneer drug,<sup>33</sup> and they establish procedures through which generic producers may challenge the validity or scope of pioneer patents.<sup>34</sup> The Canadian law and regulations, however, differed from the Hatch-Waxman Act in their omission of provisions for extending the patent term that compensate the pioneer firms for regulatory delays.<sup>35</sup> Although the Canadian legislation also omitted the incentive of the quasi-exclusive periods given to first generic challengers, it took another route towards making generics more available. It authorized generic producers to stockpile generic drugs in readiness for the expiration of the patent.<sup>36</sup> Indeed, these differences in the Canadian legislation are interrelated. Parliament’s decision not to provide for a patent-term extension to compensate for regulatory delays appears related to its decision to allow stockpiling, in that in combination, these decisions erode the patentee’s protections at both ends of the patent term. The regulatory delay makes the patent commercially unusable during its early years, the omission of patent-term extension ensures that the protected period is shortened by the full amount of the regulatory delay, and the stockpiling provision means that generic manufacturers will be ready to enter the market with a full inventory at the end of the patent term. This denies the patentee even the compensation afforded by the preparation time necessary for its generic rivals to enter the market.

The European Union challenged the stockpiling legislation before the WTO as inconsistent with Canada’s obligations under the TRIPS Agreement.<sup>37</sup> In its challenge, the European Union contended that the stockpiling legislation was properly seen in the context of Canada’s decision not to provide patent term extensions to compensate for regulatory delays.<sup>38</sup> The European Union prevailed in its challenge to the stockpiling

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31. *Id.* § 355(j)(5)(B)(iv).

32. Patent Act, R.S.C., ch. 23, § 55.2(1) (1993) (Can.).

33. Patented Medicines (Notice of Compliance) Regulations § 5(1).

34. *Id.*

35. *See* 35 U.S.C. § 156 (2004).

36. Patent Act § 55.2 (repealed). 2001 Annual Statutes of Canada, Ch. 10 (Bill S-17).

37. REPORT OF THE PANEL CANADA—PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS, 2000 WL 301021, \*1 (W.T.O.).

38. *Id.* at \*11.



provision.<sup>39</sup> However, it failed in an accompanying challenge to the provision allowing generics to use patented products to prepare their cases for regulatory approval.<sup>40</sup> As a result of the European Union's successful WTO challenge to the stockpiling provision, the Canadian Parliament repealed it.<sup>41</sup>

The successful European Union challenge to the Canadian stockpiling provision reveals the interrelations among the several welfare-enhancing policies identified above. When the Canadian Parliament shortened the effective term of pharmaceutical patents, it put the short-term interest of Canadian residents ahead of the long-term worldwide goal of stimulating innovation in pharmaceutical products. From a purely domestic perspective, this position makes sense. The Canadian market is sufficiently small that a reduction of the patent term to pharmaceutical producers would not significantly affect their incentives to innovate.<sup>42</sup> So, by enforcing the rules even in the case of a breach that in itself would not have undermined the worldwide intellectual property system, the European Union helped to ensure that the Canadian deviation would not be repeated. Moreover, the European Union's challenge also highlighted the fact that the TRIPS Agreement was part of the overall WTO trade agreement. By providing protection to the intellectual property that is currently the comparative advantage of developed nations, it helps ensure their cooperation in continuing movement towards freer trade under the WTO.

#### B. AN ECONOMIC AND POLITICAL PERSPECTIVE ON THE CANADIAN PATENT LAW MODIFICATION

When the United States and Canada imposed time-consuming regulatory responsibilities upon their pharmaceutical regulatory authorities (the U.S. Food and Drug Administration and Health Canada), the result was that the effective period of patent protection for pharmaceutical products was reduced, because patentees could not legally market those products during the initial years of the patent period when they were still awaiting regulatory approval. This effective reduction of the patent period reduced the potential profits of patentees, with a concomitant reduction of incentives. As we observed above, Congress responded to this reduction of the patent period at the beginning by legislating a compensatory extension at the end of the period.<sup>43</sup> The legislation extending the patent term did not fully compensate for the initial reduction in the patent term, because protection at the end of the term is *prima facie* less valuable than protection at the beginning. The innovation-inducing function of the patent system is premised upon the system's incentive effects and the incen-

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39. *Id.* at \*174.

40. *Id.* at \*174.

41. Act to Amend the Patent Act (Bill S-17), Assented to 14 June, 2001, codified as R.S., C. P-4, §§ 45, 78.1, 78.2, 78.4, 78.5.

42. Of course, if the Canadian example were followed by many other jurisdictions, their incentives might be affected.

43. See 35 U.S.C. § 156 (2004).

tive effects take place from the viewpoint of the potential innovator, prior to its commitment of assets to its research activities. That viewpoint, accordingly, assesses potential future profits discounted to their value at the time when assets are committed to research, i.e., at the beginning. In short, the compensatory patent-term extension replaces years of high value protection with years of low value protection. In addition, Congress also placed some limits on the extension: no extension can exceed five years and the total period encompassed by the remaining patent term plus the extension period cannot exceed fourteen years.<sup>44</sup> So, the compensatory extension patently does not fully compensate for the loss due to regulatory review. The legislation permitting generic competitors to "piggy-back" on the research of the pioneer and providing them permission to produce the materials necessary to obtain regulatory approval, of course, also somewhat shortens the patentee's effective period of exclusivity.

The effects of the United States patent-term extension legislation can be illustrated as follows. We assume that the approval of the Patent and Trademark Office ("PTO") takes two years and that FDA approval takes an additional four years. Although all patentees must wait for approval, patentees other than pharmaceutical companies are free to market their products during the waiting period. Because a pharmaceutical company cannot market its product without FDA approval, it must seek approval from both the PTO and the FDA and may not market its product until it has obtained the latter's approval. In an example in which the pharmaceutical company loses two years to the PTO and four years to the FDA, Congress has provided for a patent-term extension for the four years involved in waiting for the FDA approval.

Assume further that patent revenues are a constant amount (\$m) for each year in which the product is marketed. The company's revenues for this product then—in the absence of a patent term extension—would be as follows:

return		return		return		return	
year 1	-0-	year 6	-0-	year 11	\$m	year 16	\$m
year 2	-0-	year 7	\$m	year 12	\$m	year 17	\$m
year 3	-0-	year 8	\$m	year 13	\$m	year 18	\$m
year 4	-0-	year 9	\$m	year 14	\$m	year 19	\$m
year 5	-0-	year 10	\$m	year 15	\$m	year 20	\$m

The patent term extension changes the revenue picture to the following:

44. *Id.* § 156(c)(3).

return		return		return		return			
year 1	-0-	year 6	-0-	year 11	\$m	year 16	\$m	year 21	\$m
year 2	-0-	year 7	\$m	year 12	\$m	year 17	\$m	year 22	\$m
year 3	-0-	year 8	\$m	year 13	\$m	year 18	\$m	year 23	\$m
year 4	-0-	year 9	\$m	year 14	\$m	year 19	\$m	year 24	\$m
year 5	-0-	year 10	\$m	year 15	\$m	year 20	\$m		

The returns from years twenty-one through twenty-four are intended to compensate the patentee for the effective loss of the years three through six. But, however well intentioned, the legislation does not provide an effective scheme of compensation, given the purposes of the patent law to promote innovation. Had the patentee been permitted to exploit its patent in years three through six, its expected profits in those years would have a substantially higher value than the expected profits from years twenty-one through twenty-four, the years of the patent term extension.

The patent law promotes innovation by providing the prospect of an economic reward to the innovator. The structure of this incentive mechanism requires that the reward be assessed at the beginning, i.e., at the time that the innovator decides to commit resources to the research effort that it hopes will ultimately culminate in a successful product, producing a stream of revenues that compensates it for its research costs and the risks involved, and, in addition, produces a profit. It is at this initial period that the innovator weighs the risks against the potential revenue stream. Thus, the projected revenue stream must be discounted to its present value as of the commencement of the project.

Restating the revenue stream in terms of the present discounted value of the future revenue stream looks like this:

year 1	-0-	year 9	$\$m/(1+r)^9$	year 17	$\$m/(1+r)^{17}$
year 2	-0-	year 10	$\$m/(1+r)^{10}$	year 18	$\$m/(1+r)^{18}$
year 3	-0-	year 11	$\$m/(1+r)^{11}$	year 19	$\$m/(1+r)^{19}$
year 4	-0-	year 12	$\$m/(1+r)^{12}$	year 20	$\$m/(1+r)^{20}$
year 5	-0-	year 13	$\$m/(1+r)^{13}$	year 21	$\$m/(1+r)^{21}$
year 6	-0-	year 14	$\$m/(1+r)^{14}$	year 22	$\$m/(1+r)^{22}$
year 7	$\$m/(1+r)^7$	year 15	$\$m/(1+r)^{15}$	year 23	$\$m/(1+r)^{23}$
year 8	$\$m/(1+r)^8$	year 16	$\$m/(1+r)^{16}$	year 24	$\$m/(1+r)^{24}$

The present value of years twenty-one through twenty-four are substantially less than the present value of years three through six, as is apparent from the higher valued exponent on the denominator (and thus the greater the denominator and the lower value of the entire term). The extension compensates high value years with low value years:

year 3	$\$/\text{(1+r)}^3$	>	year 21	$\$/\text{(1+r)}^{21}$
year 4	$\$/\text{(1+r)}^4$	>	year 22	$\$/\text{(1+r)}^{22}$
year 5	$\$/\text{(1+r)}^5$	>	year 23	$\$/\text{(1+r)}^{23}$
year 6	$\$/\text{(1+r)}^6$	>	year 24	$\$/\text{(1+r)}^{24}$

The Hatch-Waxman Act extension thus suggests that it compensates patentees, but in fact it does not. It is puzzling why Congress legislated in a way that obscured its decision to undercompensate pharmaceutical patentees.<sup>45</sup> The answer may lie in the complex political context in which this legislation was enacted. The pharmaceutical companies wanted compensation for the effective loss of the early years of the patent term due to the FDA regulatory delay. However, they probably deemed it politically impractical to ask for full compensation, since that would have entailed an extension period greater than the delay. Moreover, they would be opposed by consumer groups, focusing on the short-term welfare of their members who would have ridiculed an analysis that reduced the value of the extension years to their present value. In that context, Congress was responding to the pressures of both groups. The legislation both gives to the pharmaceutical companies (by extending the patent term) and takes from them (by fostering patent challenges and the entry of generics). That was probably the best that the pharmaceutical companies could obtain.

An analysis of corresponding Canadian law is more straightforward. The absence of a powerful research-based pharmaceutical industry meant that the Canadian Parliament faced pressure from just the consumer direction. The logic of arguments based upon future global benefits engendered by patent protection is likely to succumb to the demands of consumer groups asserting their present interest in lower drug prices. The short-term interests of Canadians is furthered when the rights of pharmaceutical companies are curtailed. The actions of Parliament and the Health Minister that curtailed the patent rights of the pharmaceutical companies (denial of patent-term extension and stockpiling) are thus unproblematic. They become more problematic when they are assessed against the standard of global long-term welfare. But the democratic political process is less likely to produce an optimum result when it addresses long-term welfare. And it is even less likely to respond optimally to global welfare concerns, at least when global welfare is not an exact match to domestic welfare.

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45. Congress sometimes legislates in ways that create the appearance that it is legislating for the benefit of the larger society while it actually casts the legislation in terms that benefit organized lobbying groups. See, e.g., MURRAY J. EDELMAN, *THE SYMBOLIC USES OF POLITICS* 40 (1964).

### III. THE FREE MOVEMENT OF GOODS AND INTELLECTUAL PROPERTY WITHIN THE EUROPEAN COMMUNITY: AN UNRESOLVED DILEMMA

Within the European Union the interplay between the treaty provision protecting the free movement of goods,<sup>46</sup> varying terms of intellectual property protection, the exhaustion doctrine, and varying regulatory controls has made significant inroads upon the incentive structure of intellectual property laws. Because the pharmaceutical companies have been subjected to different degrees of regulation in the several nations within the European Union, they have borne an especially heavy burden. In the early years of the Common Market, many European nations did not recognize patents over pharmaceutical products. Patent rights over pharmaceutical products were recognized in the United Kingdom and Ireland in statutes and case law prior to the establishment of the Treaty of Rome.<sup>47</sup> But that was not true for most other European countries. Germany recognized pharmaceutical patents only in 1967, Italy in 1978, Denmark in 1983, Norway in 1992, Greece in 1992, Spain in 1992, and Finland in 1995.<sup>48</sup> Although all of the member nations now provide patent protection to pharmaceutical products, the market for these products has been, and continues to be, subject to various kinds of government intervention. As a result, prices vary substantially from country to country. These substantial price variations help to create the conditions for arbitrage.

The wide range of drug prices was illustrated in *Merck & Co. v. Stephar BV*.<sup>49</sup> That case involved large-scale purchases of a pharmaceutical product in a low-price national market and resales in a high-price market.<sup>50</sup> The particular drug involved (and on which Merck held patents) was for the treatment of hypertension.<sup>51</sup> Merck marketed it under the trademark "Moduretic."<sup>52</sup> Evidence submitted by the defendant showed price variations among seven countries.<sup>53</sup> Taking the price in the Federal Republic of Germany as a reference price at 100, the prices in other nations were: Netherlands 140; Denmark 76; Belgium 102; United Kingdom 58; France

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46. Consolidated Version of the Treaty Establishing the European Community, Articles 28-30. O.J. C. 325, 24 Dec. 2002.

47. Pharmaceutical patents were recognized in the United Kingdom in *Acetylene Illuminating Co. v. United Alkali Co.* 1905 R.P.C. 145, 153, and in the Patents Act 1949, § 4(7). Ireland recognized such patents in its Patents Act 1964, § 2. Prior to that time the Irish courts may have been influenced on this issue by the House of Lords decision in *Acetylene Illuminating Co., supra*, which was rendered prior to Irish independence. See *Merck v. Primecrown Ltd*, 1996 E.C.R. I-6285, 6317-18, n.64. (opinion of Advocate General).

48. See *Merck v. Primecrown Ltd, supra* note 47, at 6317-18, nn.64-69. The history of Italian patent protection is discussed in *Merck & Co. v. Stephar BV*, 1981 E.C.R. 2063, 2065.

49. 1981 E.C.R. 2063.

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.*

51; and Italy 56.<sup>54</sup> The low prices in France were apparently due to price controls exerted by the French government.<sup>55</sup> The low prices in the United Kingdom were apparently the result of government market interventions.<sup>56</sup>

The basic structure of the law governing the arbitrating of patented pharmaceutical products was established in 1974 in *Centrafarm BV v. Sterling Drug, Inc.*<sup>57</sup> well before universal recognition was accorded to patents on these products. That case involved patents owned by Sterling Drug, Inc., a New York corporation, on a product (acidum nalidixicum) used for treatment of urinary passage infections and marketed under the trademark "Negram."<sup>58</sup> Sterling owned patents in the United Kingdom and the Netherlands.<sup>59</sup> As in the case of many drugs, prices in the United Kingdom were substantially less than in the Netherlands.<sup>60</sup> Indeed, the United Kingdom price was one-half of the Netherlands price.<sup>61</sup> Prices were also lower in Germany than they were in the Netherlands.<sup>62</sup> Centrafarm purchased Negram in the United Kingdom and in Germany and shipped it to the Netherlands where it resold it at higher prices.<sup>63</sup> Sterling sought to bar Centrafarm from importing the product into the Netherlands on the ground that its Netherlands patent rights gave it exclusive control over the product in that country.<sup>64</sup> Sterling's position was rejected, however, by the Court of Justice which ruled that Sterling's patent rights over the particular products subsequently imported into the Netherlands were exhausted when it or its subsidiaries sold them in the United Kingdom and in Germany.<sup>65</sup> Indeed, exhaustion is a corollary of the treaty provision guaranteeing the free movement of goods. Once a person acquires title to goods, that person is free to sell them throughout the European Union.<sup>66</sup> That right of resale includes goods subject to intellectual property rights, so long as the rights-holder has authorized their

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54. *Id.* at 2075.

55. See VALENTINE KORAH, *EC COMPETITION LAW AND PRACTICE* 261 (7th ed. 2000).

56. *Id.*

57. *Centrafarm BV & Adriaan de Peijper v. Sterling Drug Inc.*, 1974 E.C.R. 1147, 2 C.M.L.R. 480.

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 1149.

62. *Id.*

63. *Id.*

64. *Id.*

65. The rule that a patentee's rights over a particular physical product are exhausted after the sale of that product has been observed in many jurisdictions. See, e.g., *Cyril Corp. v. Intel Corp.*, 846 F. Supp. 522, 538 (E.D. Tex.), *aff'd*, 42 F.3d 1411 (Fed. Cir. 1994) (applying exhaustion doctrine in the United States). A national court ruling that patent rights over a particular physical product were exhausted by a sale within that nation is applying a doctrine of domestic exhaustion. A court ruling that patent rights over a physical product were exhausted by a sale abroad is applying a doctrine of international exhaustion. Although this is technically true, the Union itself is analogous to a federation in which "domestic" jurisdiction extends throughout the federation.

66. 1974 2 C.M.L.R. at 503.

initial sale.<sup>67</sup> Sterling's second line of attack against Centrafarm was based on trademark.<sup>68</sup> Sterling contended that it had the exclusive right over the Negram trademark in the Netherlands and that this right was infringed when Centrafarm imported Negram-branded drugs into that nation.<sup>69</sup> Sterling again lost on similar reasoning by the court.<sup>70</sup> Once a product is sold with the consent of the trademark owner, the purchaser is free to resell it anywhere in the European Union.<sup>71</sup>

Later, the court reached a similar decision in *Merck & Co. v. Stephar BV*.<sup>72</sup> In this case, it was the absence of patent protection in Italy that caused the problem for Merck.<sup>73</sup> Merck sold its "Moduretic" drug in Italy even though it had been unable to secure patent protection there.<sup>74</sup> At the time the case was decided, Italy had restored patent protection for pharmaceuticals,<sup>75</sup> but the restoration was too late for Merck's product which was then in widespread public use. Stephar BV, an importer, purchased Moduretic in Italy and resold it at higher prices in the Netherlands, undercutting Merck.<sup>76</sup> Like Sterling in the earlier case, Merck wanted to employ its Netherlands patent to bar the imports from Italy.<sup>77</sup> Although Merck had hoped that because no patent protection was available in Italy the court would distinguish *Centrafarm*, its hopes were disappointed. The court ruled that the treaty provision guaranteeing the free movement of goods throughout the European Union prevented the patent law of any member state from barring the importation of those goods.<sup>78</sup> In essence, the court told Merck that if it chose to sell its goods in Italy where there was no patent protection, then it had to bear the consequences. Later decisions have refined these rules, holding, for example, that exhaustion will not destroy a patentee's right to exclude products that the importer has obtained unlawfully or without the consent of the patentee.<sup>79</sup> *Centrafarm* was reaffirmed by the Court of Justice in its 1996 decision in *Primecrown*.<sup>80</sup>

*Primecrown* involved the purchase of pharmaceutical products sold by Merck in Spain and Portugal, at a time before those countries offered

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67. 1974 2 C.M.L.R. at 503-04.

68. See *Cetrafarm BV & Adriaan de Peijper v. Winthrop BV*, 1974 E.C.R. 1183, 2 C.M.L.R. 480.

69. Sterling had raised the issue in a Netherlands court. That court referred the question to the Court of Justice. See *id.* at ¶ 1.

70. *Id.* at ¶ 7.

71. *Winthrop BV*, *supra* note 68, at ¶ 10.

72. See *supra* note 50.

73. See *supra* note 50, at 2063.

74. See *id.* at 2063.

75. Indeed, Italy had abolished patent protection over pharmaceuticals in 1939. Article 14(1) of the Italian Patent Law (Royal Decree of 29 June 1939, No. 1127). Italy did not reinstate such protection until 1978, when the Italian Constitutional Court invalidated the earlier law. See discussion in *Merck & Co. v. Stephar BV*, 1981 E.C.R. 2063, 2065.

76. See *supra* note 50, at 2063.

77. See *id.*

78. *Id.*

79. *Merck & Co. v. Primecrown Ltd.*, 1996 E.C.R. I-6285, at ¶ 41.

80. *Id.*

patent protection to pharmaceuticals, and their resale in the United Kingdom.<sup>81</sup> Merck sought to bar the importation of the products from Spain and Portugal by invoking its UK patent rights.<sup>82</sup> In its argument, Merck contended that the lack of patent protection in those countries exerted a depressing effect on prices, thus exacerbating its exposure to arbitrage.<sup>83</sup> The Advocate General, however, recognized that this argument had wider implications: that its logic would ultimately apply to the lower prices compelled by government price controls and other market interventions. His request that the court overrule *Centrafarm* broadly can perhaps be understood in that light.<sup>84</sup>

Critics have charged that the application of the exhaustion doctrine by the Court of Justice has undermined the incentive function of the patent laws, as they apply to pharmaceuticals.<sup>85</sup> Valentine Korah sees it anomalous that while the Council of the European Union is trying to strengthen intellectual property protection, the Court of Justice is reducing that protection through its reaffirmation of the *Centrafarm* line of decisions.<sup>86</sup> Korah is concerned that this line of decisions frustrates patentees from earning the rewards that the patent system promises and, accordingly, undermines its incentive structure. In asking the court to overrule *Centrafarm* in the *Primecrown* case, the Advocate General took a similar line of argument. Critics have further charged that the *Centrafarm* rule forces the national policy that is least protective to the pharmaceutical companies upon the other nations, thus engendering a kind of race to the bottom in intellectual property protection.<sup>87</sup>

In the critics' view, the court has ignored the different commercial realities between patented pharmaceutical products and other products.<sup>88</sup> The interpretative path taken by the Court of Justice encourages arbitrage. Generally this makes sense. Strict application of Article 28 to all commerce assists in the erosion of national barriers and the creation of a common market. Here arbitrage (now aided by the Euro as a common currency that increases the visibility of price differences) helps to erode separate national markets. But the intensive (and inconsistent) regulation applied by the member nations to pharmaceuticals itself helps to generate separate markets for those products. The strict application of Article 28 to pharmaceuticals would only make sense if the European Union also sought to adopt a common policy on price control and similar market interventions for pharmaceutical products. A common price control policy would produce a common, albeit regulated, market. Alterna-

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81. *Id.*

82. *Id.*

83. *Id.*

84. 1996 E.C.R. I-6285 (opinion of Advocate General).

85. See Korah, *supra* note 55, at 262, 272-73.

86. See *supra* note 57, at 278.

87. See, e.g., Andreas Reindl, *Intellectual Property and Intra-Community Trade*, 20 FORDHAM INT'L L.J. 819, 833-34 (1997).

88. Valentine Korah, *Consent in Relation to Curbs of Parallel Trade*, 25 FORDHAM INT'L L.J. 972, 973 (2002).



tively, an unregulated free market in each nation would also produce a European Union common market. In either case, arbitrage would disappear.

But, the European Union has taken neither position. It is apparently willing to live with a system in which the pricing of pharmaceutical products is subject to differing national policies and consequently are sold in different national markets. As a result, in the view of the critics, the court appears to be applying an exhaustion doctrine in a way that serves no purpose at all.<sup>89</sup> Article 28 generally helps to create a common market in most (unregulated) goods.<sup>90</sup> However, a strict application of Article 28 to products like pharmaceuticals that are subject to differing systems of national regulation appears to undermine the marketing of the patentees without an underlying justification. At least, that is the charge that is made by some critics.<sup>91</sup> It is true that the pharmaceutical companies are learning to operate within this system. Companies such as Bayer have begun limiting their sales to distributors within each member state to their estimates of national consumption.<sup>92</sup> Combined with member-state requirements that local distributors maintain stocks adequate for national needs,<sup>93</sup> this policy effectively impedes arbitrage. The Court of Justice has recently ruled that this practice is lawful under Article 81(1) of a European version of the *Colgate* doctrine, since no concerted action is involved.<sup>94</sup> The limited ability of the companies to avoid the consequences of a European Union policy fostering arbitrage, however, does not provide a rationale for an internal trade policy that appears designed to undermine the intellectual property policies of the member states. Why do the European Union authorities not take steps to bring their trade, intellectual property and healthcare policies into alignment?

Let us consider the European Union *Centrafarm* rule in the light of the incentive structure of patent (and other intellectual property) law. That rule certainly facilitates arbitrage and, thus, may help to undermine the patentee's prices in a high-price market. Thus, if we were to take the position that overall welfare is furthered when the patent mechanism fosters pharmaceutical research, we would favor overruling *Centrafarm*. This is a strong anti-*Centrafarm* position based upon the long-term welfare effects of patent law. But if we took that position, we would also want to abolish interventions in the market by governments through price controls or other devices designed to hold pharmaceutical prices to low levels. However, that position is a policy position that would be politi-

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89. See Korah, *supra* note 55, at 262 ("That is not a reason, but a conclusion.").

90. See Daniela Caruso, *Limits of the Classic Method: Positive Action in the European Union After the New Equality Directives*, 44 HARV. INT'L L.J. 331, 378 (2003).

91. See, e.g., Korah, *supra* note 55, at 272-73; Korah, *supra* note 88, at 972-73. Korah has repeatedly expressed her view that patented pharmaceuticals should be treated differently from other products under Article 28, because they are subjected to differing price regulations in the different member states.

92. *Bundesverband der Arzneimittel-Importeure v. Bayer*, 2004 O.J. (C 59) 2.

93. See *id.* at ¶ 110.

94. See *Bayer*, *supra* note 92, at ¶ 141.

cally justified only by viewing the aggregate interests of the European Union as a whole (rather than the separate interests of the individual nations composing it). Any one nation, especially smaller ones without a domestic pharmaceutical industry, may find that its interest lies in ensuring low prices in the present. The incentive effect of high prices in that country alone is minimal. Thus, on a balance between present welfare and future welfare, the balance for such a nation falls on the side of maximizing present or short-term welfare. Since the nations of the European Union do not agree on pharmaceutical policy, there is no European Union-wide option. It follows that each constituent nation must be free to follow its own interest.

A tentative conclusion thus emerges. There can be no EU-wide policy on pharmaceuticals because the interests of the member states are not aligned. In order for a common policy to emerge, the member states would have to engage in significant bargaining, trading off some interests in pharmaceutical policy for compensating benefits in other areas. This might be done at one of the periodic revisions of the Treaty of Rome or perhaps through the European Council. In the meantime, all parties have to live with existing policy differences. But, given these policy differences, should the least protective national policy be allowed to undermine the more protective national policies? Or should the nations with the more protective policies be allowed to preserve them against the undermining potential of arbitrage? The latter position is a weak anti-*Centrafarm* position: it favors overruling *Centrafarm* not on substantive policy grounds but on the grounds of protecting national autonomy. If we opt for the latter position (which is the position of the critics and the Advocate General), then do we give up on the goal of a common market for pharmaceuticals? That is, do we recognize that the *Centrafarm* rule is merely a symbolic, but ineffective, gesture towards that end? I suggest that there is a middle ground: one that recognizes the policy differences among the member states of the European Union and at the same time recognizes the importance of fostering a common market among all products, including pharmaceuticals. To make the case for this third position, I draw from the United States experience, comparing the law and economics prevailing in the United States with the situation within the European Union.

The doctrine of international exhaustion applied in the European Union appears similar (albeit not identical) to the approach of the United States courts. Thus, the United States Supreme Court has ruled that trademarked items sold abroad by a United States enterprise or its subsidiaries or licensees can be lawfully imported into the United States.<sup>95</sup> A similar rule applies to copyrighted goods.<sup>96</sup> Although the law appears less clear in the case of patents, there is ground for believing that the same rule applies to the importation into the United States of patented

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95. *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988).

96. *Quality King Distrib., Inc. v. L'anza Research Int'l, Inc.*, 523 U.S. 135, 145 (1998).

goods produced with the consent of the United States patentee.<sup>97</sup> Goods, however, that have been produced under a patent license in which the license terms confine the rights conferred upon the licensee to a specific geographic area may be treated differently. It is clear that a patentee may restrict a license geographically, and the law specifically contemplates assignments of geographical rights.<sup>98</sup> But, it remains unclear whether a purchaser from a licensee or assignee of geographical limited rights, who has purchased the patented product abroad, may import the product into the United States. Yet, this problem is perhaps more theoretical than real, because United States patent owners could minimize the prospect of importation by forbidding their foreign licensees to sell to purchasers who refuse to provide assurances that they will not ship to the United States.<sup>99</sup>

The European and United States laws are also similar in their provisions dealing with the free movement of goods within their jurisdiction. The European Union's Article 28 that bars quantitative restrictions on imports by member states has a parallel in the Commerce Clause of the United States Constitution<sup>100</sup> that prevents individual states from barring imports from other states.<sup>101</sup> The purpose of both provisions is the same: the establishment of a "common market"<sup>102</sup> throughout the larger jurisdiction.

Despite the similarities, United States law differs significantly from European law in its impact. While the United States and Europe appear to apply the exhaustion doctrine in a similar manner, the presence in the European Union of different national markets that result in part from differing regulatory regimes has no parallel in the United States. While there are differences in the structure of health insurance among the states of the United States and minor differences in the regulation of healthcare providers, these differences do not appear to have generated separate geographical markets for pharmaceutical products. This is not to say that all such products are sold at the same price to all buyers. Retail prices vary substantially as a result of bargaining by health maintenance organizations, insurance companies, large employers, drug store chains and others whose patronage is important to the pharmaceutical companies.<sup>103</sup>

97. *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*, 266 F. 71, 78 (2d Cir. 1920).

98. 35 U.S.C. § 261 (2004).

99. *See Gen. Talking Pictures Co. v. W. Elec. Co.*, 304 U.S. 175, 181-82 (1938) (recognizing that license limitations can prevent licensee from conveying title to a third party).

100. U.S. CONST. art. I, § 8, cl. 3.

101. *See, e.g.*, Daniel J. Gifford, *Federalism, Efficiency, the Commerce Clause, and the Sherman Act: Why We Should Follow a Consistent Free-Market Policy*, 44 EMORY L.J. 1227 (1995); Daniel A. Farber & Robert E. Hudec, *Free Trade and the Regulatory State: A GATT's Eye View of the Dormant Commerce Clause*, 47 VAND. L. REV. 1401 (1994).

102. *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 423 (1994).

103. *See In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 783 (7th Cir. 1999); *United States v. Costanzo*, 4 F.3d 658, 659-60 (8th Cir. 1993); *United States v. Ferro*, 252 F.3d 964, 967 (8th Cir. 2001). *See ROY LEVY, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF*

Discount pharmacies and internet pharmacies help to pass on these lower prices to their customers. Retail prices are also subsidized by insurance companies to their insureds. Yet, these sometimes wide variations in the prices of pharmaceutical products take place within a single geographic market.

The United States experience suggests a way of reacting to the European Union caselaw that takes account of political differences within the European Union and, yet, would help to foster a common market in pharmaceuticals. Critics like Korah assert that the court's decisions undermine the incentives of the pharmaceutical companies to develop new drugs.<sup>104</sup> She makes these assertions because she focuses upon the arbitrage effects: Shipments from low price countries into high-price countries undermine the patentee's high prices in the latter.<sup>105</sup> But the United States provides a counter example. No one contends that the market in the United States is segmented geographically. Yet, prices in the United States vary widely as already noted. Moreover, prices in the United States are affected by the large purchases made through the Medicaid program and the controls that the federal and state governments exert over Medicaid pricing.<sup>106</sup> The federal government through the Department of Veterans Affairs also wields buying power to obtain substantial discounts.<sup>107</sup> Because governments purchase drugs for use by those who would otherwise be unable to afford them, they have raised the demand for drugs, generating an upward pressure on their prices. Conversely, because the governments are large buyers, they can and do exert downward pressure on prices through their purchases.<sup>108</sup> It would be possible for the nations of the European Union to follow approximately the same policies that they are now following, if the nations that now impose price controls were to substitute government purchases at negotiated prices. There is no reason to believe that the pharmaceutical companies that choose to market their products in nations imposing price controls would not be willing to sell them to government agencies in those nations at negotiated prices that were identical to the present regulated prices. In such cases, the companies would probably tailor the quantities sold to the needs of the particular nation, thus minimizing the prospect of arbitrage,

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CHANGE 78-79 (FTC Bu. Econ. Staff Rep't, Mar. 1999) (reporting that for 1994, hospitals paid an average of 91% of price paid by retail pharmacies, HMOs paid 82%, and federal facilities paid 58%).

104. See *supra* note 57, at 278.

105. *Id.*

106. On Medicaid pricing see generally 42 U.S.C. § 1396r-8 (2004) (incorporating rebate norm of difference between manufacturer's average and "best" prices to independent purchasers). On state efforts at price control see generally Pharm. Research & Mfrs. Ass'n v. Walsh, 538 U.S. 644 (2003), and Pharm. Research & Mfrs. Ass'n v. Meadows, 304 F.3d 1197 (11th Cir. 2002), *cert. denied*, 538 U.S. 1056 (2003).

107. See, e.g., Steven Kelman, *Buying Commercial: An Introduction and Framework*, 27 PUB. CONT. L.J. 249, 256 (1998) (reporting that by switching to a single national contract for the purchase of a particular pharmaceutical, the Department of Veterans Affairs reduced its cost from \$2.5 million to \$500,000).

108. See *supra* notes 106 and 107.

in the manner that Bayer and others are doing now.<sup>109</sup> But sales to a government agency for domestic needs would probably more closely approximate national needs than the present system that depends upon the manufacturer's estimates and sets of distributors that are actively trying to misinform the manufacturer in the interest of securing larger supplies for export to higher-priced states.

This approach would be consistent with the incentive structure of patent law. The incentive structure of patent law is premised upon the market. There is no assumption that bargaining cannot take place in the market. Indeed, the exclusive rights accorded to the patentees assumes that the patentees will bargain hard in their dealings with licensees and customers. Conversely, the market premise of patent law is also consistent with hard bargaining by customers, especially large customers. The attraction of this possible middle approach is that it is fully consistent with the incentive structure of patent law, that it is supportive of a common market in pharmaceuticals, and that it respects policy differences among the member states.

Under the middle-ground approach advocated here, each nation of the European Union that wished to intervene in the market for pharmaceutical products would do so through negotiation and bargaining with the pharmaceutical companies over prices, terms of sale, dates of delivery, and quantities purchased. Other purchasers (i.e., nongovernmental purchasers) would also be free to negotiate with the pharmaceutical companies as well. As explained, this scenario would likely produce results no less favorable to consumers than those now obtaining in the various member states of the European Union. Yet this scenario would also be more compatible with a common market

#### IV. IMPEDIMENTS TO THE FUNCTIONING OF INTELLECTUAL PROPERTY LAWS: THE DOUBLE EDGE OF JUDICIAL TREATMENTS OF BIOTECHNOLOGY PATENTS

Biotechnology innovation has been protected in the United States by the Plant Patent Act of 1930 (providing protection for asexually reproduced plants)<sup>110</sup> and the 1970 Plant Variety Protection Act (extending protection to sexually reproduced plants).<sup>111</sup> The Supreme Court's 1980 decision in *Diamond v. Chakrabarty*<sup>112</sup> upheld the patentability under the general patent law of genetically-engineered organisms, thus, fostering the development of the biotechnology industry. In the wake of *Chakrabarty*, the critical issues affecting biotechnology patents have been resolved in the United States Court of Appeals for the Federal Circuit.

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109. See *supra* note 94.

110. 35 U.S.C. §§ 161-64 (2004).

111. 7 U.S.C. § 2321 (2004).

112. 447 U.S. 303, 310 (1980).

European and American laws governing patents in general and biotechnology inventions in particular employ similar concepts. Both sets of laws require novelty and a substantial advance before providing protection to an invention,<sup>113</sup> and both employ the concept of a skilled professional in the relevant field as a baseline for measuring the substantiality of that advance.<sup>114</sup> Nonetheless, the two systems appear to operate quite differently and to embrace significantly different policies.

The United States law has entwined the protection of biotechnology advances in a doctrinal mix involving description, enablement, obviousness and equivalence. Thus, like the European law, the United States patent law extends protection only to inventions that are “non-obvious,”<sup>115</sup> inventions which are beyond the ability of a skilled professional working in the field. Like the European law, it also requires that a patent application contain a written description of the invention in terms that are sufficiently clear and precise as to enable a skilled person to make and use it.<sup>116</sup> In the United States, these traditional requirements of patentability have taken on some new characteristics as they apply to biotechnology.

Much of the work in biotechnology involves the DNA structure and its relation to the creation of proteins. DNA is essentially the blueprint used by living organisms to create the proteins needed in the process of life. The Federal Circuit has taken a two-pronged approach to the patentability of DNA molecular structure. First, the court has taken the position that a DNA structure which cannot be described cannot be obvious.<sup>117</sup> This approach, in combination with the redundancy of the genetic code, has meant that DNA structures have been treated as nonobvious and therefore patentable, even though the corresponding amino acid structure of the related protein was generally known.<sup>118</sup> Knowledge of the

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113. 35 U.S.C. § 102 (2004) (novelty), § 103 (nonobviousness); European Patent Convention (“EPC”), art. 54 (novelty), art 52(1) (inventive step).

114. 35 U.S.C. § 103 (2004); EPC, art. 56.

115. 35 U.S.C. § 103(a). See EPC, arts. 52(1), 56.

116. Section 111(A) requires the patent application to contain a specification as prescribed by § 112. 35 U.S.C. § 111(A) (2004). Section 112 requires that the specification contain a “written description” of the invention “and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .” 35 U.S.C. § 112 (2004). The latter is commonly referred to as the enablement requirement. The European analogue to § 112 is EPC art. 83, which requires the application to “disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.” Its description requirement is contained in EPC, art. 80(d). As in § 112, the EPC requires that the claims be supported by the description. See EPC, art. 84.

117. *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995) (“What cannot be contemplated or conceived cannot be obvious.”); *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993). In incorporating the description requirement into the nonobviousness standard, the Federal Circuit has, in effect, lowered the standard of nonobviousness and thereby facilitated patent grants. See Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 55 (1992) (advocating a modest reduction in the nonobviousness standard in areas of high-cost research to encourage such research).

118. *In re Deuel*, *supra* note 117; *In re Bell*, *supra* note 117.

protein structure does not reveal the actual DNA structure, because a potentially wide variety of DNA structures might theoretically produce the given protein structure. This part of the Federal Circuit's approach, which has facilitated the patenting of DNA molecular structure,<sup>119</sup> has provided support to the biotechnology industry, encouraging work on the identification and isolation of a multitude of DNA structures.

The second prong of the court's approach, however, may produce an opposite effect. In a mirror image of its approach to the obviousness of a DNA structure, the court has read § 112's description provision as requiring, as a condition of patentability, that each link in the claimed DNA segment be identified. Thus, for example, in the *Eli Lilly* case,<sup>120</sup> the University of California had claimed patents on the DNA structure for human insulin, vertebrate insulin and mammalian insulin. The University's claim for human insulin failed because the specification lacked a written description of its subject matter.<sup>121</sup> The University had described only the cDNA of rat insulin in its specification, along with a method for obtaining human cDNA plus the amino acid sequences of human insulin A and B chains.<sup>122</sup> The court ruled that whether or not this disclosure was enabling, it was deficient because it did not "provide a written description of the cDNA encoding human insulin,"<sup>123</sup> and thus, failed to satisfy the description requirement in §112. The University's claims for vertebrate and mammalian insulin also failed the written description requirement because the specification contained a description only of the cDNA of a species (rat insulin) and not of either of the claimed genera.<sup>124</sup>

These failures to describe the DNA structures rendered the University's claims invalid, even though the court conceded that its patent application may have supplied information sufficient to enable a skilled professional to obtain human insulin.<sup>125</sup> The Federal Circuit's emphasis upon a full description of the molecular structure is an outgrowth of its approach to chemical patents, especially those involving inorganic com-

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119. Professors Dan Burk and Mark Lemley argue that while lowering the standard of nonobviousness is good policy towards fields afflicted by uncertainty and high research costs, the uncertainty and costs afflicting the biotechnology industry is not generally at the stage of the initial research that produces the invention but, at the post-patent stage in bringing the product through the hurdle of FDA regulation to market. They therefore urge that the Federal Circuit adopt a very different approach to biotechnology inventions than the one that they have been following. They urge a reduced description requirement and high standards of nonobviousness. This approach would produce fewer but more valuable patents. The higher-value patents would facilitate the investment needed to navigate through the post-patent development stage, and the lower number of patents would avoid anticommons problems that might be generated by a multiplicity of DNA patents. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1680-83 (2003).

120. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

121. *Id.* at 1567.

122. *Id.*

123. *Id.*

124. *Id.* at 1567-68.

125. *Id.* at 1567 ("Whether or not [the specification] provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin. . . .").

pounds or simpler organic compounds. In dealing with ordinary chemical compounds, the court rightly has insisted upon a complete description of molecular structure and has been more willing to infer obviousness when the claimed compound is structurally similar to one or more previously known compounds.<sup>126</sup> Its refusal to draw the same inferences of obviousness in the case of DNA is based in the greater complexity of DNA structure and its redundancy. Yet, while the court recognizes the differences between DNA and non-DNA structures for purposes of obviousness, it imposes the same description requirements for both DNA and non-DNA compounds.<sup>127</sup>

The court's critics believe that this approach to the description requirement places biotechnology companies in a difficult position that may inhibit their research activities.<sup>128</sup> If a company rushes its discovery to the patent office, it may be able to obtain a patent only upon one variety of a DNA structure for a beneficial protein, while enabling its competitors to use its research—now publicly revealed in its patent—to produce unprotected equivalents. Yet, delay may mean that a rival will either identify the DNA sequence on another variety or even the DNA sequences common to the genus. Either way, the risk that research results will be economically unprotectable is increased. Concomitantly, the incentives to research are undermined.

The problem of the *Eli Lilly* case results from the greater stringency placed upon the description requirement relative to the enablement requirement. Yet, the ability to describe is not unrelated to enablement. At least in the case of the claim involving human insulin, the claim failure appears to have been the fault of the University.<sup>129</sup> But will the ruling in that case generate other decisions that discourage research as the critics fear? That is, will the decision delay patent filing? Will it foster an environment in which rivals “free-ride” off of an innovator's research by producing slightly different but similarly-functioning DNA molecules? In United States patent law, the judicially-developed doctrine of equivalents has been the primary mechanism designed to protect patentees against free-riding on another's invention in situations in which the other does not literally infringe.<sup>130</sup> But the scope of the doctrine of equivalents is in

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126. *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990).

127. *Eli Lilly*, *supra* note 120, at 1566-67.

128. See Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 736-38 (2004) (arguing that the present severe description requirement unduly limits the scope of biotechnology patents; and that the biotechnology industry would benefit from a policy under which the standards for nonobviousness were raised and the scope of issued patents were widened).

129. If its disclosure enabled the production of the cDNA for human insulin, then, with some additional work, it could have supplied the required description.

130. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950). See also Steven H. VerSteen, *Parallel Applications to Preserve the Doctrine of Equivalents in a Post Festo World*, 84. PAT. & TRADEMARK OFF. SOC'Y 341, 353 (2002) (noting that the doctrine of equivalents prevents . . . freeriding by a competitor.”)



doubt and its future is cloudy.<sup>131</sup>

Traditionally, an invention is the equivalent of another if it is structurally the same and one or more elements—although literally different from the patented invention—are interchangeable with the elements recited in the claim, and the interchangeability would be known by a skilled professional.<sup>132</sup> Recent cases, however, have introduced complications into that doctrine. The courts have been concerned that a patentee might intentionally narrow its claims while it is seeking Patent Office approval and then later, in the context of an infringement suit, seek to recover what it had surrendered through a judicial application of the doctrine of equivalents.<sup>133</sup> In order to prevent this kind of strategic behavior, the courts have created the doctrine of prosecution estoppel, which bars such a patentee from using the equivalence doctrine to recover the protection that it had earlier surrendered in negotiations with the Patent Office.<sup>134</sup>

The doctrine of equivalents was recently applied at the protein level to an Amgen composition of erythropoietin glycoprotein.<sup>135</sup> In that case, Amgen had mistakenly claimed a protein with a 166 amino-acid sequence.<sup>136</sup> The protein initially possessed a 166 sequence, but at the time that it became ready to perform its work in the body, it had shed one sequence. The alleged infringer had produced a protein with the 165 amino-acid sequence that performed similarly to Amgen's. Because the rival's product lacked one of the amino acids identified in Amgen's claim, it did not literally infringe. Nonetheless, the district court upheld Amgen's infringement claim under the doctrine of equivalents.<sup>137</sup>

Yet, the doctrine of equivalents ultimately proved unavailable to Amgen.<sup>138</sup> During the patent prosecution, Amgen amended its application to distinguish its claims from another patent that had already been issued to it. Because this amendment was not made for any reason related to the statutory patent requirements, the district court found the amendment innocuous.<sup>139</sup> On appeal, however, the Federal Circuit ruled that this amendment—because it was made for a patent related reason—estopped Amgen from using the doctrine of equivalents.<sup>140</sup> The appellate decision in *Amgen* thus suggests that the doctrine of equivalents may po-

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131. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 535 U.S. 722 (2002); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345 (Fed. Cir. 2003).

132. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

133. *Festo Corp.*, 535 U.S. at 733-34; *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30-31 (1997).

134. *Festo Corp.*, 535 U.S. at 733-34; *Warner-Jenkinson Co.*, 520 U.S. at 30-31.

135. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 99-100 (D. Mass. 2001), *aff'd in part and rev'd in part*, 314 F.3d 1313 (Fed. Cir. 2003).

136. See 314 F.3d at 1343 ("At the time the patent was drafted, it was believed that the sequence included 166 amino acids. . . . In fact, the full sequence was actually 165 amino acids; the last (arginine) is actually cleaved off prior to the protein's secretion from the cell.").

137. *Id.* at 1344.

138. 314 F. 3d at 1345.

139. 126 F. Supp. 2d at 134.

140. 314 F.3d at 1345.

tentially have a more limited applicability than it has previously been understood to possess. Because of the complex structural characteristics of DNA and protein, the current incarnations of the doctrines of obviousness, and the recently enhanced description requirement appear to leave DNA and protein claims vulnerable to free-riding, in the absence of strong protection under the doctrine of equivalents. The erosion of the latter doctrine, therefore, appears to strike at the heart of biotech patent protection.

The European approach to biotechnology patents appears so far to have avoided the doctrinal morass of the American decisions. In several decisions the Technical Board of Appeal has upheld biotech patents that made broad claims that were cast in functional language,<sup>141</sup> indicating that the European system may be more encouraging of biotechnical research than the U.S. system.<sup>142</sup> Some decisions of the European Technical Board of Appeal appear to be sensitive to the dilemma generated by the *Eli Lilly* decision. In *Biogen/Recombinant DNA*, for example, the Board justified the use of functional language on the ground that “[u]nless claims with such functional connotations are allowable, no worthwhile protection is provided against a third-party which faithfully repeats the process of the patent and obtains new but equally useful variants of the invention.”<sup>143</sup> Yet, while tolerant of functional language, the European system is careful to limit protection—like United States law—to the scope of that which can be enabled. The difference then is that the United States system adds an enhanced description requirement.<sup>144</sup> If this enhanced description requirement does inhibit research as the critics fear, then United States courts will have made a wrong turn in the *Eli Lilly* case.<sup>145</sup>

A stylized version of this problem can be represented as follows: The number of vertebrates is  $n$ , and thus, the number of vertebrate insulin DNA structures is also  $n$ . A patent covering the genus of vertebrate DNA structures would extend to all  $n$  structures. Because a patent of generic scope could not be easily avoided, its value would be the present value of the income stream generated by the use of DNA for the produc-

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141. See *Genentech I/Polypeptide Expression*, [1989] E.P.O.R. 1, 7 (1988) (“It follows that the features may generically embrace the use of unknown or not yet envisaged possibilities, including specific variants which might be provided or invented in the future.”); *Biogen/Recombinant DNA*, [1990] E.P.O.R. 190, 202 (1989) (“Unless claims with such functional connotations are allowable, no worthwhile protection is provided against a third-party which faithfully repeats the process of the patent and obtains new but equally useful variants of the invention.”). See also *Mycogen*, [1998] E.P.O.R. 114, 120, 125 (1996). The reader will observe that this approach is consistent with the policy recommendations of Burk and Lemley for biotechnology patent policy. See Burk & Lemley, *supra* note 119.

142. See, e.g., LI WESTERLUND, *BIOTECH PATENTS: EQUIVALENCY AND EXCLUSIONS UNDER EUROPEAN AND US PATENT LAW* 121-23 (2002) (discussing *Eli Lilly* and comparing the strictness of European and United States approaches to biotechnology patents).

143. [1990] E.P.O.R. at 202.

144. 35 U.S.C. § 112 (2004).

145. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

tion of insulin of all types. Assuming that stream is  $m$  dollars per year, that value could be represented as follows:

$$\sum_{i=3}^{20} \$m/(1+r)^i.$$

But a patent relating to the DNA of only one species would have a scope of only  $1/n$  of the genus patent. Since, in theory,  $(n-1)/n$  of the scope of the genus patent would be open to rivals to produce freely, the initial species patent would represent exclusive rights over only an insignificant share of the commercially valuable genus. Indeed, it is possible that, following the doctrine that what cannot be described cannot be obvious, the rivals might each patent their own DNA variants. In any case, the market in insulin would be transformed into a fully competitive market and the initial patentee and its rivals would compete away their rents. Thus, the incentives for research provided by the patent system would be illusory.

Because DNA patents are a relatively new phenomenon, it is to be expected that new issues will emerge in the application of preexisting doctrine. To a large extent, as the preceding discussion has shown, these are issues of patent scope arising under the rubrics of obviousness, enablement, description, and equivalents. They involve the courts in working out the interrelationships among these doctrines in ways that fit the complexities of the DNA contexts. They are not easy tasks, yet the welfare goals underlying the patent system can sometimes provide needed guidance. As the courts come to a better understanding of the technology, they will be better able to formulate these various doctrines in ways that support (rather than undermine) the incentive structure of the patent system.

## V. THE SCOPE OF COMPUTER PROGRAM PROTECTION AND THE PROBLEM OF THE ANTI-COMMONS

Although computer programs currently receive protection in the United States under both patent and copyright laws, that has not always been the case. The protection of computer programs in the United States did not begin until the 1980s.<sup>146</sup> During the previous decade, patent protection appeared to be unavailable, as the Supreme Court caselaw appeared to be saying that patentable subject matter did not include "mathematical algorithms,"<sup>147</sup> suggesting to many observers that computer programs could not be protected under patent law. Moreover, the 1976 revision of United States copyright law contained no provision protecting computer programming. Only in 1980 did Congress amend the

146. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

147. *Parker v. Flook*, 437 U.S. 584, 586, 594 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972).

copyright law to provide protection for computer programs.<sup>148</sup> And, only in 1981 did the Supreme Court relax its hostility towards the protection of computer programs under patent law.<sup>149</sup>

The Court's more tolerant attitude towards computer programs was expressed, in 1981, in its *Diamond v. Diehr* decision that upheld the patentability of a process for curing rubber inside a mold, even though a component of the process involved a computer (using a well-known mathematical formula) to continuously update the curing time as a result of temperature inputs from within the mold.<sup>150</sup> In *Diehr*, the Court characterized the patent as pertaining to an industrial process and, thus, to subject matter that has been traditionally protected by patent law.<sup>151</sup> Because the computer program in *Diehr* was only a part of a larger process, the Court was able to uphold the patentability of the process without repudiating its earlier assertions that algorithms themselves were unprotectable. The *Diehr* decision then made possible the Federal Circuit's aggressive protection of computer programs throughout the 1990s.

In 1994, the Federal Circuit upheld a patent for transforming discrete electronic inputs into a smooth waveform display in a digital oscilloscope, despite the fact that the invention consisted almost (if not quite entirely) of a computer algorithm.<sup>152</sup> The court, however, reasoned that computer programming can transform general purpose computers into specialized machines to perform particular functions.<sup>153</sup> In this case, the programming transformed discrete data into a smooth curve on a standard monitoring device.<sup>154</sup> Extending the scope of patentable programming even further, the court in its 1998 *State Street Bank* decision upheld the patentability of a computer program for implementing a financial structure for mutual funds.<sup>155</sup>

Most computer programs, when protectable under patent law, receive their protection at a higher level of abstraction than simple machine or source code.<sup>156</sup> Patent applications involving computer programs are generally stated in means-plus-function language, in an effort to obtain protection that includes the implementation of a functional element of the invention by any computer program, a strategy that will succeed so long as the patent office and the courts view inventions incorporating other programs implementing that function as equivalents. Because both the patent office and the courts currently view most programming as the implementation of a simple skill common to all or most programmers,

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148. See 17 U.S.C. § 101(1) (2004).

149. 450 U.S. at 185.

150. 450 U.S. at 185.

151. *Id.*

152. *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir. 1994).

153. *Id.*

154. *Id.*

155. *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

156. See discussion of standards for software patents in Burk & Lemley, *supra* note 119, at 1688.

and because patentees rarely describe their programs at the level of source code in the patent specifications, this strategy is likely to be successful. In this context, the difficulties that the Supreme Court had experienced in the past over the protection of algorithms are minimized, because it is not the particular algorithm that generally constitutes the patented invention; rather, the invention consists in the performance of the function by that or any equivalent algorithm.

Protection for computer programming at the level of code and code structure is generally a function of copyright law.<sup>157</sup> Computer programs are treated as “literary works” under United States copyright law,<sup>158</sup> an approach that, given the essentially utilitarian nature of programming, is somewhat at odds with the tradition of copyright as the protector of the literary and artistic. Yet, copyright protection has the advantage of narrow protection. Copyright protection does not extend to ideas,<sup>159</sup> reserving protection for major innovations to patent law. Moreover, because it protects only against copying, the copyright regime guarantees freedom for independent creation. A major social disadvantage to copyright protection of computer programs, however, is the extensive period of protection, a period that at least in the case of programming is far too long.<sup>160</sup>

The lack of copyright protection for computer programs in the 1970s was particularly unfortunate because the personal computer industry was in its gestation and early stages of growth during this period, and software firms were vulnerable to free-riding.<sup>161</sup> Another consequence of the absence of copyright protection for software was the exposure of operating systems to fragmentation, a potential that was realized in the case of the Unix operating system, developed by American Telephone & Telegraph Co. in its Bell Laboratories in the 1970s. Unix was extensively employed by many firms and individuals, many of whom introduced their own modifications to the program, with the result that various versions of Unix emerged. This created a circumstance in which one version would not necessarily interact with other versions, at least without problems.<sup>162</sup> Because operating systems become more useful and hence valuable as their common-user base increases, Unix—despite its great value—has fallen short of its potential.

Here, accordingly, was another market failure and one that was the direct result of the absence of an effective intellectual property regime.

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157. 17 U.S.C. § 101(1) (2004).

158. See *Whelan Assocs. v. Jaslow Dental Lab.*, 797 F.2d 1222, 1234 (3d Cir. 1986).

159. 17 U.S.C. § 102(6) (2004).

160. See 17 U.S.C. § 302 (2004) (life of author plus 70 years; 95 years from first publication for work-for-hire, anonymous work, or pseudonymous work).

161. See *Bill Gates, An Open Letter to Lobbyists*, in STEPHEN MANES & PAUL ANDREWS, *GATES: HOW MICROSOFT'S MOGUL REINVENTED AN INDUSTRY AND MADE HIMSELF THE RICHEST MAN IN AMERICA* 91-92 (1993). The incident giving rise to Gates' letter is described in John Markoff, *A Tale of the Tape From the Days When it Was Still Micro Soft*, N.Y. TIMES, Sept. 18, 2000 at C1.

162. Howard A. Shelanski & J. Gregory Sidak, *Antitrust Divestiture in Network Industries*, 68 U. CHI. L. REV. 1, 87 (2001).

In the so-called new economy, certain kinds of software—especially operating systems—possess characteristics that facilitate user interaction with each other and with commonly-used software application programs. As a result, widespread use of the same operating system creates a virtual network that increases the software's value as its user base increases. Fragmentation of the operating system erodes, shrinks or destroys that virtual network, erasing the value that it would otherwise have possessed. It is one of the functions of intellectual property rights to protect network-generating software against the kinds of modifications that threaten the network. Unix's potential as network-generating software was eroded because Bell Laboratories was unable to assert control over the modifications. The 1980 legislation that provided copyright protection to software created the property rights that are essential to guarding against fragmentation.<sup>163</sup> Today, the Microsoft Corporation asserts control over its Windows operating system through copyright and other intellectual property rights, preventing users from modifying it in ways that undermine its usefulness as an operating system. Similarly, Sun Microsystems, Inc. uses copyright and trademark certification to protect its Java platform from fragmenting.<sup>164</sup> Copyright is even being employed to rehabilitate Unix as AT&T and Sun attempt to reassert control over that software.<sup>165</sup>

Even after Congress provided copyright protection to software, the scope of that protection remained uncertain. It took a number of years for the courts to work out standards of protection that met the industry's needs. Initially, the scope of protection that copyrighted programs received from the courts was far too broad. In 1987, the Third Circuit in *Whelan*<sup>166</sup> took the position that the purpose or function of the program was its unprotectable idea, and that everything else constituted protectable expression. Five years later, however, the Second Circuit in *Altai*<sup>167</sup> modified *Whelan*'s approach by identifying the purpose of each routine and subroutine of the larger program as an unprotectable "idea." Then, the elements of the routine or subroutine that implemented their purposes would be protectable so long as they were not required for efficient operation, were not standard routines in common use, and were not re-

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163. 17 U.S.C. § 101(1) (2004).

164. Sun's concerns over fragmentation underlay its litigation with Microsoft, its complaints about the latter to the Justice Department. Sun saw Microsoft's creation of a Window's specific version of Java and Microsoft's handling of Java's native calls as generating fragmentation that ultimately would destroy Java as an alternative platform. *Sun Microsystems, Inc. v. Microsoft Corp.*, 188 F.3d 1115, 1118, 1120 (9th Cir. 1999), *vacating and remanding* 21 F. Supp. 2d 1109, 1115 (N.D. Cal. 1998). See also *Sun Microsystems, Inc. v. Microsoft Corp.*, 87 F. Supp. 2d 992, 996-97, 1005 (N.D. Cal. 2000) (on remand). The Justice Department also shared these concerns. See *United States v. Microsoft Corp.*, 84 F. Supp. 2d 9, 105-110 (D.D.C. 1999) (findings 386-407).

165. *Addamax Corp. v. Open Software Found.*, 152 F.3d 48, 49-50 (1st Cir. 1998). See also discussion in ROBERT AXELROD ET AL., *Setting Standards: Coalition Formation in Standard-Setting Alliances in THE COMPLEXITY OF COOPERATION* 96, 107 (Robert Axelrod ed., 1997).

166. *Whelan Assocs., Inc. v. Jaslow Dental Lab., Inc.*, 797 F.2d 1222, 1238 (3d Cir. 1986), *cert. denied*, 479 U.S. 1031 (1987).

167. *Computer Assocs. Int'l, Inc. v. Altai, Inc.*, 982 F.2d 693, 706 (2d Cir. 1992).

quired for external reasons, such as the requirements of the hardware.<sup>168</sup> The court described this kind of analysis as an abstraction-filtration-comparison test.<sup>169</sup> First, the court followed an abstraction approach by identifying several levels (routines, subroutines, etc.) where it would perform the rest of its analysis.<sup>170</sup> At each level the court identified the unprotectable idea and the elements that were unprotectable for reasons of efficiency, standard usage, external constraints or public domain, and filtered them out.<sup>171</sup> Then the court compared what was left, the protectable elements, with the corresponding elements of the accused program, to determine the extent (if any) of infringement.<sup>172</sup>

The abstraction-filtration-comparison test narrows copyright protection significantly. As a consequence, the potential for copyrights in existing programs to interfere with efforts of programmers in constructing new programs is minimized. Built into the *Altai* test is permission to use whatever is necessary for efficiency reasons and to employ all of the standardized modules familiar to programmers.<sup>173</sup> And, of course, programmers can legitimately employ whatever is necessary for the hardware or for interoperability. While remaining faithful to the law's prohibition against copying, the court in *Altai* also ensured that copyright law will not be employed to create barriers to creativity. Indeed, the problem symbolized by the anti-commons—impediments to innovation raised by an abundance of preexisting intellectual property rights—appears to have been minimized by that decision and its progeny.

The potential for copyright to reduce social value (rather than to encourage the creation of new social value) has been further lowered as a result of both caselaw and legislation that allow reverse engineering of computer programs for the purpose of achieving interoperability. Several decisions now recognize that right.<sup>174</sup> In the Digital Millennium Copyright Act,<sup>175</sup> Congress included a provision excluding reverse engineering for achieving interoperability from its otherwise general prohibitions against circumvention of copyright protection systems.

The First Circuit's *Lotus* decision further constrains the ability of copy-

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168. *Id.* at 707-10.

169. *Id.* at 706-12.

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.* at 707-09.

174. *Sony Computer Entm't, Inc. v. Connectrix Corp.*, 203 F.3d 596, 602 (9th Cir. 2000); *Sega Enters. Ltd. v. Accolade, Inc.*, 977 F.2d 1510, 1519 (9th Cir. 1992); *Atari Games Corp. v. Nintendo of Am., Inc.*, 975 F.2d 832, 843 (Fed. Cir. 1992). *Lewis Galoob Toys, Inc. v. Nintendo of Am., Inc.*, 964 F.2d 965, 972 (9th Cir. 1992), *cert. denied*, 507 U.S. 985 (1993) also supports the broad proposition that the courts have not favored the use of copyright to exclude products produced by others from interacting with protected software.

175. 17 U.S.C. § 1201(f) (2004). In its provisions prohibiting the circumvention of copyright protection systems, the Digital Millennium Copyright Act included an exception for reverse engineering for the purpose of achieving interoperability.

right to reduce social value.<sup>176</sup> In *Lotus*, a rival had copied the command structure of the Lotus spreadsheet program to reduce the learning costs that would be imposed upon users of Lotus who wished to switch to the rival's spreadsheet program.<sup>177</sup> No social purpose would be advanced by protecting the command structure.<sup>178</sup> Indeed, protecting the command structure would have conflicted with the law's manifest purpose of encouraging programming; the law has no purpose of encouraging the imposition of learning costs upon consumers. The *Lotus* decision highlights the coincidence of copyright protection with the furtherance of social welfare.<sup>179</sup>

In short, the phenomenon of the anti-commons identified in the literature is a theoretical construct in which intellectual property rights work perversely by creating barriers to innovation. At least in the copyright protection of computer programs, this possibility seems to be minimized by caselaw that limits the extent to which programs are protectable. The abstraction-filtration-comparison test of infringement appears to bar the protection of programming elements that are required by other programmers; a line of cases explicitly allows copying necessary to achieving program interoperability; and the *Lotus* decision—by denying protection where aggregate social value would be reduced by protection—provides confirmation that the courts will resolve most disputed issues in copyright coverage in a way that furthers, rather than reduces, social welfare.<sup>180</sup>

Patent protection, however, raises more difficult problems. In an invention in which the computer program performs a function that is only one out of several functional elements, as in the rubber-curing invention involved in *Diamond v. Diehr*,<sup>181</sup> the computer program remains available for use by others in different contexts. But, where the primary operational element of the invention is the program and that program has only one highly specialized use, as in *State Street Bank*,<sup>182</sup> where the program determined and allocated investment fund values, not only that program, but all other programs performing the same function may well be off-limits to other inventors. Note that the patentee does not ordinarily describe the program in its specification at the level of source code.<sup>183</sup> Rather, the program is usually described in terms of its structure which itself often takes the form of describing relationships between various

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176. *Lotus Dev. Corp. v. Borland Int'l Inc.*, 49 F.3d 807 (1st Cir. 1995), *aff'd*, 516 U.S. 233 (1996).

177. *Id.*

178. *Id.*

179. *Id.*

180. In their discussion of patent law, Burk and Lemley expressed the concern that because software develops through incremental improvements, small improvements should be protected. Burk & Lemley, *supra* note 119, at 1689. That function may be presently performed by copyright law.

181. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

182. *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

183. *See supra* note 156.



functions.<sup>184</sup> Thus, the higher the level of structural description contained in the specification, the broader is the range of actual programs that will fall within the scope of equivalents to it.

Yet, unexplored areas of patent law may limit what potentially would otherwise be too broad an area of protection. It is only the equivalents of the program that are treated as an element of the protected invention. The traditional test for equivalence is satisfied when “[an alternative] performs substantially the same function in substantially the same way to obtain the same result.”<sup>185</sup> If an alternative program is sufficiently structurally different as to negate equivalency under the triple-identity test, then a rival device employing the alternative program will not infringe.<sup>186</sup> In context, this would be the case when the alternative program produced the same result but in a structurally different “way.” Thus, although patent protection of computer programs possesses the potential for overprotection,<sup>187</sup> there is a little room for maneuver. The extent to which this theoretical room for maneuver can in fact be realized awaits further development of the caselaw.

#### VI. RESTRICTIONS ON THE EXERCISE OF EXCLUSIVE RIGHTS UNDER MISUSE AND ANTITRUST LAWS: WELFARE EFFECTS

Both the patent and copyright misuse doctrines are judicial creations designed to prevent intellectual property rights from being used contrary to the purposes of those laws. The misuse doctrine entered patent law in the first quarter of the twentieth century as a judicial attempt to incorporate antitrust concerns into the patent law.<sup>188</sup> It was in this context that the courts developed the language that condemned an attempt to “extend” a patent beyond the terms of its grant.<sup>189</sup> The courts generally conceptualized misuse as the leveraging of the “monopoly” conferred by a patent into a second market where the patentee uses its power over the patented product to compel a purchaser (or licensee) to purchase (or license) a second product. In the last decade of the twentieth century, the courts adopted a copyright misuse doctrine modeled upon the earlier patent misuse doctrine.

184. *See id.*

185. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608 (1950) (citing *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)); *see also Pennwalt Corp. v. Durand-Wheland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987), *cert. denied*, 485 U.S. 961 (1988).

186. *Graver Tank & Mfg. Co.*, 833 F.2d at 608-09.

187. Overprotection of software is one of the concerns raised by *Burk & Lemley*. *See Burk & Lemley*, *supra* note 119, at 1688-89.

188. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 517-18 (1917) (referring to policies embodied in Clayton Act § 3 in process of overruling *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912)). *See Daniel J. Gifford, Antitrust's Troubled Relations with Intellectual Property*, 87 MINN. L. REV. 1695, 1705-08 (2003) (describing development of the misuse doctrine).

189. *Motion Picture Patents Co.*, *supra* note 188, at 429; *Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 33-35 (1931).

## A. PATENT MISUSE

The patent misuse doctrine reached its apogee in the *Mercoïd* cases of the 1940s.<sup>190</sup> In those cases the Supreme Court condemned practices employed in marketing thermostats by the Honeywell Corporation. Honeywell sold thermostats in packages that carried a license authorizing purchasers to construct certain patented heating systems.<sup>191</sup> The Court characterized this marketing as involving the patented heating system as the tying product and the thermostat as the tied product.<sup>192</sup> It then condemned the arrangement in sweeping terms.<sup>193</sup> Indeed, the Court's rhetoric was so broad that it undermined the doctrine of contributory infringement, a patent doctrine dating back into the nineteenth century. In response, Congress enacted legislation restoring the doctrine of contributory infringement and imposing stringent limits on the development and application of the misuse doctrine by the courts.<sup>194</sup>

These legislative constraints on the misuse doctrine have enabled patentees to better exploit their patents. Often, arrangements that the courts have conceptualized as problematic tying arrangements have in fact been dictated by the practicalities of marketing and have been efficiency-enhancing. In the *Mercoïd* cases, for example, the Court condemned as misuse and unlawful tying the sale of unpatented thermostats together with licenses to use the thermostats in the construction of patented heating systems.<sup>195</sup> In so doing, the Court effectively ignored Honeywell's inherent expertise in manufacturing thermostats. Society's welfare would not be enhanced by requiring Honeywell to market heating systems. Indeed, the customers were likely to be able to install the heating system more efficiently than Honeywell, or to be able to contract with an efficient installer.<sup>196</sup> In *Rohm & Haas*,<sup>197</sup> the company possessed a patent over the use of propanil as a herbicide. The patentee was best able to market its process by selling propanil to farmers, together with a license to use it as an herbicide.<sup>198</sup> Indeed, this method of marketing minimizes distribution costs. No social purpose would be furthered by requiring the company to sell process licenses to farmers.<sup>199</sup>

In short, the dimensions of the misuse doctrine changed over time in accordance with changes in institutional understandings of social welfare. First, the courts created the misuse doctrine to condemn tying arrange-

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190. See *Mercoïd Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944); *Mercoïd Corp. v. Minneapolis-Honeywell Regulator Co.*, 320 U.S. 680 (1944).

191. The patented heating systems involved a furnace, thermostat, and furnace override. See 320 U.S. at 664.

192. See *id.* at 666-67.

193. See *id.* at 667-68, 678.

194. See 66 Stat. 811, ch. 950 (1952). That legislation and its subsequent amendment have given us the present § 271 of the patent act. 35 U.S.C. § 271(d) (2004).

195. See *Mercoïd Corp.*, 320 U.S. at 666; *Mercoïd Corp.*, 320 U.S. at 684.

196. *Mercoïd Corp.*, 320 U.S. at 661; *Mercoïd Corp.*, 320 U.S. at 680.

197. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 198 (1980).

198. *Id.* at 183.

199. *Id.*

ments that they viewed as reducing social welfare.<sup>200</sup> Later, Congress modified that doctrine when it concluded that at least some tying arrangements were legitimate for the exploitation of patents.<sup>201</sup>

## B. COPYRIGHT MISUSE

In its 1990 *Lasercomb* decision,<sup>202</sup> the United States Court of Appeals for the Fourth Circuit resurrected the doctrine of copyright misuse, which had been largely neglected up to that time. Asserting that the copyright law was sufficiently similar to the patent law to justify incorporating a copyright analogue to patent misuse, the court justified its new doctrine, to a large extent, on the basis of the judicial decisions that had created the patent misuse doctrine.<sup>203</sup> Yet the court did not feel constrained by the legislative limits that Congress had placed on patent misuse. Moreover, the court construed its new doctrine expansively. Under the court's approach a copyright is misused—and therefore unenforceable—whenever it is licensed with a restriction that the court deems to impose a restraint.<sup>204</sup> Thus, in the *Lasercomb* case, the owner of a copyright on cad/cam software (computer aided design-computer aided manufacturing) licensed it to a manufacturing company, providing in the licensing agreement that during the term of the agreement the licensee would be prohibited from designing cad/cam software.<sup>205</sup> The licensor justified the restriction on the ground that it helped to protect itself against licensees who sought to divert its work product for their own use. The Fourth Circuit, however, rejected that justification, asserting that no rule-of-reason defense should be recognized in the application of the misuse doctrine.<sup>206</sup> In a later case, the Ninth Circuit followed that approach, finding misuse where the copyright owner had entered into an exclusive licensing agreement with a licensee.<sup>207</sup>

## C. INTELLECTUAL PROPERTY, THE MISUSE DOCTRINES AND SOCIAL WELFARE

When the courts initially created the misuse doctrine, they were attempting to ensure that the exclusive rights conferred by the intellectual property laws would not be “extended” beyond the scope that Congress intended. That is another way of saying that—given the assumptions of

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200. *Mercoïd Corp.* 320 U.S. at 661; *Mercoïd Corp.*, 320 U.S. at 680.

201. 35 U.S.C. § 271(d) (2004).

202. *Lasercomb Am., Inc. v. Reynolds*, 911 F.2d 970, 976 (4th Cir. 1990).

203. *Id.* at 976-77.

204. *See id.* at 979.

205. *Id.* at 978.

206. *Id.* at 977.

207. *Practice Mgmt. Info. Co. v. Am. Med. Ass'n*, 121 F.3d 516, 520 (1997). The Third Circuit has recently indicated that it is taking a less expansive approach to the doctrine of copyright misuse. *See Video Pipeline, Inc. v. Buena Vista Home Entm't, Inc.*, 342 F.3d 191, 203-06 (3d Cir. 2003), *cert. denied*, 124 S. Ct. 410 (2004).

intellectual property law<sup>208</sup>—the courts were attempting to prevent the intellectual property laws from being used perversely to reduce, rather than to advance, aggregate social welfare. Consistent with this approach, the courts took an aggressively expansive approach to patent misuse during a period in which tying arrangements (which were the primary subject of the misuse doctrine) were deemed to lack social value. During the last half century, economists have come to recognize social value in tying arrangements, and coincidentally, Congress has cut back the courts' powers to condemn tying arrangements in the patent context.<sup>209</sup>

The creation of a copyright misuse doctrine by the courts in the 1990s can also be viewed as an effort by the courts to ensure that copyright not be employed to reduce social welfare. Yet, except for a qualification that I will introduce below, that effort was largely mistaken. The most significant application of the copyright misuse doctrine has been with software, and, in this area, the potential of copyright to reduce social value inheres in whatever capacity it possesses for creating an anti-commons or otherwise to impede the creation of new programming works. But, we have seen that the courts construe the application of copyright law to software as to minimize that potential.<sup>210</sup> The development of the abstraction-filtration-comparison test of infringement; the aggressive use of the fair use doctrine to foster program interoperability; and the overall openness to resolving copyright issues so as to further aggregate social value work in this direction. As a result of this enlightened approach to copyright interpretation, the need for a copyright misuse doctrine has been significantly reduced.

#### D. INNOVATION AND TYING IN AMERICAN AND EUROPEAN COMPETITION LAW

##### 1. *Under United States Antitrust Law*

In the mid-1990s, the United States Justice Department and the European Commission questioned licensing and other practices of the Microsoft Corporation. These enforcement agencies were particularly concerned about Microsoft's custom of licensing its operating systems to computer manufacturers at a lump sum amount keyed to the estimated production capacity of the licensee. This practice was often referred to as

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208. The relevant assumptions of intellectual property law are that the grant of an exclusive right for the statutory period generates the incentive to create new products that adds to aggregate welfare more than the cumulative deadweight loss detracts. In deciding upon the lengths of the patent and copyright terms, Congress is making the judgment that the social balance is positive. Judicial judgments about "extensions" as constituting misuse can be understood as judicial judgments about aggregate social welfare, given the legislative judgments about term length and other aspects of the tradeoff.

209. Not only has Congress restricted the patent misuse doctrine but the courts themselves have brought the patent misuse doctrine into close alignment with antitrust law by requiring that an impact on competition be shown as a condition for applying that doctrine. *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-02 (Fed. Cir.), *cert. denied*, 477 U.S. 905 (1986); *see supra* note 194.

210. *See supra* notes 149-96 and accompanying text.

a “per-processor” license, since the fee was calculated solely by the number of processors employed by the licensee.<sup>211</sup> Because a computer manufacturer paid for a Microsoft operating system license for each computer that it produced, regardless of whether a Microsoft operating system was actually installed on that computer, manufacturers were discouraged from installing rival operating systems. Any manufacturer that did so would have to pay twice for an operating system license: once to Microsoft under the per-processor arrangement and once to the rival operating system producer.

After the Justice Department challenged these practices in an antitrust action,<sup>212</sup> a three-way settlement was reached between the Justice Department and the European Commission on one side and Microsoft on the other. Under the settlement, Microsoft agreed to discontinue the per-processor licensing practice.<sup>213</sup> Microsoft was permitted to issue bulk licenses for identifiable lines of computers, so long as these lines did not encompass all of the licensee’s production.<sup>214</sup> The settlement also gave rise to later antitrust litigation between Microsoft and the Justice Department.<sup>215</sup>

The settlement prohibited Microsoft from “tying” one product to another, but permitted Microsoft to integrate two products together.<sup>216</sup> As the D.C. Circuit later explained, this provision was written against a background that involved complaints by Digital Equipment to the European Commission about Microsoft “tying” its Windows 3.1 graphical user interface to its MS-DOS operating system.<sup>217</sup> In the negotiations over the settlement terms, Microsoft—which had integrated the graphical user interface into its operating system in Windows 95—insisted that product integration be permitted.<sup>218</sup> And, the enforcement agencies agreed.<sup>219</sup>

Subsequently, the Justice Department, contending that Microsoft had violated the consent decree by tying its Internet Explorer browser to its Windows operating system, instituted a proceeding to hold that company in contempt.<sup>220</sup> Ultimately, the United States Court of Appeals for the District of Columbia Circuit ruled in favor of Microsoft on the ground that the browser appeared to be tied so closely to the operating system that they were integrated (and thus protected) within the meaning of the

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211. See Daniel J. Gifford, *Microsoft Corporation, the Justice Department, and Antitrust Theory*, 25 Sw. U. L. REV. 621, 632 (1996).

212. Complaint ¶¶ 19-20, *United States v. Microsoft Corp.*, Civ. A. 94-1564, 1995 WL 505998, at \*1 (D.D.C. Aug. 21, 1995). See *United States v. Microsoft Corp.*, 159 F.R.D. 318, 321 (D.D.C.), *rev'd*, 56 F.3d 1448 (D.C. Cir. 1995).

213. See 1995 WL 505998, at \*3.

214. *Id.* See definition of “per system license” at \*2. See Gifford, *supra* note 211, at 643.

215. See *infra* note 232.

216. See 1995 WL 505998, at \*3.

217. *United States v. Microsoft Corp.*, 147 F.3d 935, 950 (D.C. Cir. 1998).

218. *Id.*

219. *Id.*

220. See *United States v. Microsoft Corp.*, 980 F. Supp. 537 (D.D.C. 1997).

consent decree.<sup>221</sup>

The Justice Department's loss of the contempt proceeding did not end its challenge to Microsoft's marketing of its browser. Shortly after the D.C. Circuit's decision in the contempt proceeding, the Justice Department brought a new antitrust action, charging that Microsoft's bundling of its browser with its operating system constituted both an unlawful tying arrangement under section one of the Sherman Act as well as monopolization and attempted monopolization under section two.<sup>222</sup> Although the court of appeals ultimately upheld a ruling that Microsoft had indeed monopolized the market by combining its browser with its operating system,<sup>223</sup> it is the grounds on which the court ruled that are interesting. In effect, the court ruled that Microsoft wrongfully denied its customers (i.e., the computer manufacturers) the ability to remove the browser when they so desired.<sup>224</sup> If the products were so designed as to make that removal impossible, then Microsoft bore the burden of showing an efficiency reason for barring the disintegration of the two products.<sup>225</sup> Thus, for example, commingling the code for the operating system and the browser in the same files effectively prevented the removal of the browser, and because Microsoft was unable to justify this commingling as contributing in any way to the product's value, the court ruled that the commingling constituted an act of monopolization.<sup>226</sup>

To fully appreciate the court's monopoly ruling, it is necessary to observe that the monopolization theory underlying the Justice Department's case was somewhat unique.<sup>227</sup> Monopolization consists of acquiring or maintaining a monopoly through unlawful means.<sup>228</sup> Monopolization cases often involve a contention that a firm possessing market power has attempted to leverage that power to create a monopoly in that or another market.<sup>229</sup> Microsoft, however, was charged with monopolization through unlawful maintenance.<sup>230</sup> Although the courts have gradually worked out some standards by which to evaluate claims of unlawful acquisition, they have not developed precise standards for evaluating claims of unlawful maintenance. The D.C. Circuit dealt with the lack of standards for evaluating monopoly maintenance claims in two ways. First, it relaxed the causal standards for connecting the defendant's be-

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221. *Microsoft Corp.*, 147 F.3d at 952.

222. *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30 (D.D.C. 2000).

223. *United States v. Microsoft Corp.*, 253 F.3d 34, 66-67 (D.C. Cir. 2001).

224. *Id.* (finding that Microsoft had excluded the browser from the "Add/Remove Programs," thereby making it difficult or impossible to remove).

225. *Id.* at 67.

226. *Id.*

227. See Daniel J. Gifford, *What is Monopolization anyway? The D.C. Circuit Grapples with some Perplexing Issues*, 46 ANTITRUST BULL. 797 (2001).

228. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966) (describing monopolization as "the willful acquisition or maintenance" of monopoly power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident").

229. *United States v. Griffith*, 334 U.S. 100, 107 (1948).

230. *Microsoft Corp.*, 253 F.3d at 45.

havior and the likely market impact.<sup>231</sup> The high causal standards generally imposed in acquisition cases were deemed inapplicable. Second, it required Microsoft to come forward with a reason for combining its browser with its operating system.<sup>232</sup>

When it dealt with the section one tying issue, however, the issue became an alleged restraint of competition in the browser market. Under then-existing law, tying arrangements by a firm with market power would be condemned as per se illegal.<sup>233</sup> Microsoft possessed market power, so the issue would have been whether two products were tied together or were so integrated as to constitute only one product (so that there was no tie). That issue, in turn, depended upon whether the plaintiff could establish separate demands for the browser and the operating system. The existence of separate demands, as the test for deciding whether one or two products are involved, had been formulated by the Supreme Court in 1984, in its *Jefferson Parish* decision.<sup>234</sup>

The court of appeals, however, ruled that the separate demand test was actually a proxy for efficiency.<sup>235</sup> Normally, where integration would be more efficient, buyers would demand the combination.<sup>236</sup> But, platform software advances have often taken the form of integrating previously separate functionalities into the platform.<sup>237</sup> Since there is almost always a pre-existing software program providing functionality before that functionality is integrated into an operating system, the separate demand test would essentially treat all expansions of operating systems as ties.<sup>238</sup> The court thus concluded that the use of a separate demand test would be likely to deter efficient advances in platform software where efficiency dictated integration of new functionalities into the platform.<sup>239</sup> For these reasons, the court rejected the per se test as applied to the integration of new functionalities into platform software.<sup>240</sup> Rather, the court ruled that this type of integration would be governed by the rule of reason.<sup>241</sup> Under the rule of reason, the plaintiff bears the burden of establishing that integration of new functionalities into platform software is inefficient.<sup>242</sup>

In short, the United States Court of Appeals for the District of Columbia adopted an efficiency test for evaluating ties involving platform software under both section one and section two.<sup>243</sup> Where the charge

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231. *Id.* at 78-80.

232. *Id.* at 66-67.

233. *See id.* at 84-85.

234. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984).

235. *Microsoft Corp.*, 253 F.3d at 88.

236. *Id.*

237. *Id.*

238. *Id.* at 89.

239. *Id.*

240. *Id.*

241. *Id.*

242. *Id.* at 94.

243. *Id.*

was monopolization, the court placed the burden of showing that the design was efficient upon the defendant monopolist.<sup>244</sup> Where the issue was tying under section one, the burden of showing that the arrangement was inefficient was placed upon the government-plaintiff.<sup>245</sup> However, the court made clear that under both sections, the issue turned on the efficiency of the integration.<sup>246</sup> Restated, the issue turned upon whether combining the two products generated greater value.

## 2. Under European Competition Law

The European Commission currently appears to be taking an approach to the integration of platform software that is the mirror image of the D.C. Circuit's decision on the section one tying issue. Whereas the United States court presumed that integration of functionalities into the operating system was lawful,<sup>247</sup> the European Commission construed similar behavior as an abuse of dominant position. The issue before the European Commission involved the integration of the Windows Media Player into the Windows operating system.<sup>248</sup> That integration, of course, disadvantages independent vendors of media software, but it appears to enhance the usefulness of the operating system to the advantage of consumers, just as the integration of other functionalities into the operating system in the past has advantaged consumers. The European Commission's view, however, is that its decision will enable computer manufacturers to install media players of other brands, whenever consumer tastes so indicate.<sup>249</sup> The Commission may be viewing the Windows operating system as an essential facility to which rival software companies need access.<sup>250</sup>

The extent to which intellectual property (or an intellectual property product) may be treated as an essential facility has been at the cutting edge of European law for the last decade. In the early 1990s, the European Court of Justice ruled, in the now widely discussed *Magill* case,<sup>251</sup> that a copyright holder's refusal to license a potential competitor in a derivative market could constitute an abuse of dominant position. That case involved the refusal by several television broadcasters to make their programming schedules available to an independent publisher that wished to publish a combined programming guide.<sup>252</sup> In the early 1990s,

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244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.* at 95.

248. European Commission Press Release, Brussels, 24 March 2004 (Commission concludes Microsoft Investigation, imposes conduct remedies and a fine).

249. *Id.*

250. The court of the First Instance has rebuffed Microsoft's petition to stay the relief ordered by the Commission pending appeal. Order of the President of the Court of First Instance in case T-201/04 R, Dec. 22, 2004 (Press Release No. 103/04).

251. *Radio Telefis Eireann & Indep. Television Publ'ns Ltd. v. Comm'n*, 1995 ECR I-0743.

252. *Id.*



the television programming available to the Irish public was provided by the Irish network, Radio Telefis Eireann (RTE) (two channels), the British Broadcasting Corporation (BBC) (two channels), Independent Television (ITV), and Channel 4.<sup>253</sup> Each of these television networks published its own programming guide, but there was no comprehensive guide to all programming.<sup>254</sup>

Magill saw an opportunity to fill a demand by publishing a comprehensive programming guide. When it published its comprehensive guide however, RTE, the BBC and Independent Television Publications (the publication arm of IBA) brought suit against Magill for copyright infringement.<sup>255</sup> They sought and obtained from the Irish courts an injunction against Magill's use of their programming schedules.<sup>256</sup>

Magill, in turn, complained to the European Commission. The European Commission sided with Magill, charging that the television broadcasters were abusing dominant positions in refusing to license their schedules to Magill.<sup>257</sup> As a result of the abuse, the broadcasters were ordered to supply their television schedules to Magill at a reasonable royalty.<sup>258</sup> The European Commission's ruling was upheld by both the Court of First Instance and the Court of Justice.<sup>259</sup>

American observers are generally struck by several aspects of the *Magill* ruling. First, the Court of Justice imposed a duty on the broadcasters to license their copyrighted material to a rival that wanted to supply a product that the copyright holders themselves did not offer. Under United States law, a copyright holder normally may deny permission to others to use the copyrighted materials even in an unserved market.<sup>260</sup> American observers, however, are generally surprised that the information in the program schedules was protectable under the Irish copyright law. In the United States, such material would be considered "factual" and consequently unprotectable.<sup>261</sup> Indeed, it appears that this kind of information would not be protectable under the laws of most of the member states of the European Union.<sup>262</sup> The intriguing aspects of the *Magill* ruling, however, concern the extent to which the exclusive rights conferred by intellectual property protection can be deemed to confer a dominant position on the rights holder, with a concomitant obligation upon the rights holder to license others to use those rights.

253. *Id.* ITV and Channel 4 were both provided by the Independent Broadcasting Authority.

254. *Id.* ¶¶ 7-10.

255. *Id.* ¶ 10.

256. *Id.*

257. Independent Television Publications Ltd. V. E.C. Commission, 1991 4 C.M.L.R. 745 (CFI, 2d Chamber), *appeal dismissed*, 1995 E.C.R. I-0743.

258. *Id.*

259. *Id.*

260. Pac. & S. Co., Inc. v. Duncan, 744 F.2d 1490, 1496-97 (11th Cir. 1984); Georgia Television Co. v. TV News Clips of Atlanta, Inc., 718 F. Supp. 939 (N.D. Ga. 1989).

261. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 344-45, 347-48 (1991).

262. VALENTINE KORAH, AN INTRODUCTORY GUIDE TO EC COMPETITION LAW AND PRACTICE 119 (7th ed. 2000).

The Court of Justice has recognized that the imposition upon an intellectual property rights holder of an obligation to deal would effectively negate the exclusivity conferred by the intellectual property.<sup>263</sup> On that rationale, the Court upheld Volvo's right to refuse to license independent parts manufacturers to produce parts over which Volvo held design rights.<sup>264</sup> Yet the issue is at the core of the litigation in *IMS Health*.<sup>265</sup> The latter case involved the right to use a scheme for the classification of data relating to the use of pharmaceutical products that had been developed by IMS in connection with information-collecting activities that it was conducting for pharmaceutical companies.<sup>266</sup> IMS was the only company collecting that kind of information on a regional basis in Germany.<sup>267</sup> Its information-collection system involved the use of a large number of small geographical categories or units in which the information was kept.<sup>268</sup> When rival information-collection companies tried to compete with IMS, they discovered that because the pharmaceutical companies were already invested in using the IMS classification system, they could not effectively compete unless they could use that classification system also.<sup>269</sup> Taking the view that the IMS's classification was a de facto industry standard to which rivals were entitled to access, the Commission initially sided with the rivals, ordering IMS to license the competitors to use its classification system, pending a final decision by the Commission on its exclusivity rights.<sup>270</sup> The Court of the First Instance, however, vacated the Commission's interim order. And as of this writing, the Court of Justice has ruled that a dominant firm like IMS must license a rival only in cases in which the rival seeks to market a product different from the product of the rights-holder and when the refusal has the effect of reserving to the rights holder the entire market for the supply of pharmaceutical sales data.<sup>271</sup> The Court referred the determination of these questions to the national courts in Germany.

Valentine Korah views the Commission's interim order in *IMS Health* as an extension of *Magill*, in that the license was ordered in *Magill* to enable the entrant to meet an unserved demand, while in *IMS Health*, the license was ordered to enable new entrants to compete with an incumbent that was already supplying the desired product.<sup>272</sup> Because Korah appears to view *Magill* as an "exceptional" inroad into intellectual prop-

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263. Volvo AB v. Erik Veng (U.K.) Ltd., 1988 E.C.R. 6211.

264. *Id.*

265. Commission Decision 2002/165/EC or NDC Health/IMS Health: Interim Measure 2001 O.J. (L 59) 18,167.

266. *Id.*

267. *Id.*

268. *Id.*

269. *Id.*

270. *Id.*

271. *IMS Health Gmbh & Co. v. NDC Health Gmbh & Co.*, Case C-417 (5th Chamber) (Apr. 29, 2004)).

272. Valentine Korah, *The Interface Between Intellectual Property and Antitrust: The European Experience*, 69 ANTITRUST L.J. 801, 825 (2001).

erty rights,<sup>273</sup> her unease with *IMS Health* is not surprising.<sup>274</sup> Yet, as discussed below, it is not clear that the results in *Magill* and the Commission's approach in *IMS Health* would not be duplicated in the American legal system, albeit by different routes.

*Magill* and *IMS Health* deal with the intersection of intellectual property and competition laws. For that reason, the issues raised by these cases resonate in American law. Prior to the United States Supreme Court's clarification of the law governing the protectability of directories, one American court had ruled that the informational content of a telephone directory should be made available to a rival publisher under the essential facilities doctrine,<sup>275</sup> a decision similar to *Magill*. After *Feist*,<sup>276</sup> however, such an invocation of the essential facilities doctrine would be unnecessary in that type of case. Even so, there are other contexts in which American courts might sometimes act in ways that resemble the actions of the European Commission. In its *Kodak* decision,<sup>277</sup> the United States Court of Appeals for the Ninth Circuit effectively imposed an obligation upon an intellectual property rights holder to supply parts to competitors.<sup>278</sup> In the *Kodak* case, independent servicing organizations that wanted to service Kodak high-speed copiers and micrographic equipment were impeded from doing so because Kodak had refused to sell them replacement parts.<sup>279</sup> In subsequent antitrust litigation, Kodak defended its refusal, partially on the ground that some of the parts were patented and that its refusal was condoned by the patent law.<sup>280</sup> The Ninth Circuit agreed that Kodak's refusal was presumptively lawful, but nonetheless ruled against Kodak on the ground that the jury had implicitly found that its assertion of patent rights was merely a "pretext" for violating the antitrust laws.<sup>281</sup>

The Ninth Circuit's approach was later rejected by the Federal Circuit in a similar case involving the Xerox Corporation on the ground that it undermined intellectual property protections by making them dependent upon the subjective intent of the rights holder.<sup>282</sup> The Federal Circuit, accordingly, ruled that the patent laws conferred upon Xerox a right to refuse to supply protected replacement parts to independent service organizations and that the copyright laws gave it the right to refuse to supply copyrighted manuals to the independent servicing organizations.<sup>283</sup>

273. Korah, *supra* note 272, at 814.

274. *Id.* at 828-29.

275. *Bellsouth Adver. & Publ'g Corp. v. Donnelley Info. Pub'g, Inc.*, 719 F. Supp. 1551 (S.D. Fla. 1988), *rev'd on other grounds*, 999 F.2d 1436 (11th Cir. 1993).

276. *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340 (1991).

277. *Image Technical Serv. v. Eastman Kodak Co.*, 125 F.3d 1195, 1206 (9th Cir. 1997).

278. *Id.* at 1219.

279. *Id.*

280. *Id.*

281. *Id.* at 1220.

282. *Id.*

283. *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000), *cert. denied*, 121 S. Ct. 1077 (2001).

The litigation in both the European Union and the United States raises issues concerning the extent to which competition-law policies will be employed to override intellectual property protection. The European cases show that the authorities there are troubled by this complex issue and yet remain puzzled as to its proper resolution. The Commission appears to be aggressively pursuing competition law at the expense of intellectual property rights in both the *Magill* and *IMS Health* cases, while the Court of First Instance appears to be attempting to limit *Magill*. The Court of Justice has now taken an ostensibly narrow approach to the interpretation of *Magill*, but its decision is nonetheless cast in language that is potentially open to developing into a position resembling the Commission's.<sup>284</sup> In the United States, a close analogue to the *Magill* case would not arise because the underlying information would not be protectable.<sup>285</sup> But, it is not entirely clear how an analogue to *IMS Health* would be decided. The Seventh Circuit has protected a taxonomy of dental procedures from copying, while indicating that the categories themselves could be freely used by dentists and others.<sup>286</sup> In a similar case, the Ninth Circuit also upheld the copyright in a taxonomy of medical procedures, while indicating that copyright would not be permitted to deny access to a classification system that had become an industry standard.<sup>287</sup> These cases suggest, but do not decide, that pure *IMS Health*-type issues might be resolved in the United States in favor of the rivals' claims for access under the copyright laws themselves.

The American law differs significantly from the European law, however, because the limits on intellectual property more-often-than-not arise under the intellectual property laws, thus avoiding a clash with the antitrust laws. American copyright law is deeply influenced by principles, traditions, and even specific statutory provisions that deny protection to the utilitarian,<sup>288</sup> that exclude from protection ideas and systems,<sup>289</sup> and that treat accessibility to a system as a positive value.<sup>290</sup> In addition, the American intellectual property laws have incorporated their own competition policy concerns in their misuse doctrines. As a result, the potential

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284. The Court ruled that *IMS* is not required to license a rival so long as the rival is not offering a different product. Yet the Court did not provide criteria for determining how different the rival's product must be in order to satisfy this condition. The Court also indicated that when a refusal to license an intellectual property right reserves a connected market (such as the supply of data) to the rights holder, an important condition for finding a violation is satisfied.

285. Factual information, such as television schedules, is not protectable under United States copyright law. See *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340 (1991).

286. *Am. Dental Ass'n v. Delta Dental Plans Ass'n*, 126 F.3d 977, 979 (7th Cir. 1997).

287. *Practice Mgmt. Info. Corp. v. Am. Med. Ass'n*, 121 F.3d 516, 519 (9th Cir. 1997).

288. See 17 U.S.C. §§ 101, 113 (2004) (denying protection to the utilitarian); *Mazer v. Stein*, 347 U.S. 201, 214 (1954).

289. Pamela Samuelson, *Computer Programs, User Interfaces, and Section 102(b) of the Copyright Act of 1976: A Critique of Lotus v. Paperback*, 6 HIGH TECH. L.J. 209, 226 n.73 (1991).

290. *Sony Computer Entm't, Inc. v. Connectix Corp.*, 203 F.3d 596, 602 (9th Cir. 2000); *Sega Enters. Ltd. v. Accolade, Inc.*, 977 F.2d 1510, 1519 (9th Cir. 1992); *Atari Games Corp. v. Nintendo of Am., Inc.*, 975 F.2d 832, 842 (Fed. Cir. 1992).

conflicts between intellectual property laws and antitrust laws are reduced. Even where these two sets of laws facially conflict, antitrust law is being construed to respect intellectual property concerns. In the *Microsoft* case,<sup>291</sup> for example, the District of Columbia Circuit allowed antitrust law to trump copyright law in those instances in which the court determined that a substantial copyright policy would not be undermined, but allowed copyright law to trump antitrust law where a substantial copyright policy would otherwise be jeopardized.<sup>292</sup> Indeed, there appears to be an emerging synthesis of intellectual property and antitrust laws in which the long-term goals of intellectual property law are increasingly respected.<sup>293</sup>

An American-type synthesis of intellectual property and competition law is more difficult in Europe, because the European Union currently possesses a Union-wide competition law, but only national intellectual property laws. As a result, it is more difficult for the varying national intellectual property policies to be incorporated into the construction of Union-wide competition law. And, it is also difficult, albeit not impossible, for the national courts to incorporate European competition policy concerns into their national intellectual property laws. These impediments to harmonization, within Europe, of intellectual property law with competition law means that the interactions of these two sets of laws are likely to produce a less than efficient result. Because competition laws exist on a Union-wide scale and are enforceable by Union institutions, conflicts are likely to be resolved in favor of the competition laws; thus, sacrificing the long-term goals of intellectual property law for the shorter-term focus of competition law.

### 3. *Ramifications for the Misuse Doctrine.*

This new emphasis on efficiency as permeating the analysis of tying arrangements under both sections of the Sherman Act is likely also to influence the development of the copyright misuse doctrine. Copyright misuse should be focusing upon preventing copyright from diverting from its underlying purpose of fostering creative activity. As applied to intellectual property, the misuse doctrine would best achieve that end by incorporating an efficiency standard. The Fourth Circuit's rejection of a rule-of-reason (and hence an efficiency) analysis in the *Lasercomb* decision was a misstep.<sup>294</sup> The rejection of an efficiency standard explains the anomalous result reached by the Ninth Circuit in the *Practice Management* decision.<sup>295</sup> In *Practice Management*, the court ruled that an exclu-

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291. *United States v. Microsoft Corp.*, 253 F.3d 34, 63-64 (D.C. Cir. 2001).

292. *Id.*

293. Daniel J. Gifford, *The Antitrust/Intellectual Property Interface*, 31 HOFSTRA L. REV. 363, 414-17 (2002); Daniel J. Gifford, *Developing Models for a Coherent Treatment of Standard-Setting Issues Under the Patent, Copyright, and Antitrust Laws*, 43 IDEA 331, 388-92 (2003).

294. *Lasercomb*, 911 F.2d at 977.

295. *Practice Mgmt.*, 121 F.3d at 520.

sive supply provision in a licensing agreement constituted misuse, not because of anticompetitive effect of the contractual provision, but because that kind of restraint was combined with a copyright license.<sup>296</sup> Such decisions do nothing to further the underlying purpose of copyright law, that is, the creation of social value through the encouragement of creativity. Eventually, however, the courts are likely to modify copyright misuse doctrine in the light of their growing awareness of how the efficiency considerations that permeate antitrust law can further the underlying goals of copyright law as well.

## VII. CONCLUSIONS AND FINAL THOUGHTS

This paper has examined the policies of governmental institutions in the United States, Canada, and the European Community towards innovation. It examined several discrete problem areas with a view of developing a better understanding of how impediments to advancing aggregate welfare develop within these several political systems. In particular, the paper focused upon areas in which intellectual property concerns were inaccurately analyzed by institutional actors; where intellectual property concerns ran into conflict or potential conflict with imbedded legal doctrines; and where those concerns were undermined by conflicting political pressures. In addition to identifying several places in which governmental institutions appear to be acting to impede social welfare, the paper revealed instances in which national welfare conflicts with the aggregate welfare of a larger jurisdictional unit or with global welfare. The paper provided a possible scenario for resolving an apparently intractable policy conflict in the European Union between policies favoring the free movement of goods and policies fostering innovation. Finally, the paper showed how United States courts are gradually attaining a sophisticated understanding of intellectual property concerns and using their new awareness to rationalize several substantive areas of law impinging upon intellectual property rights; and places where judicial institutions are actually improving their levels of analysis.

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296. *Id.*

