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# Protecting Private Intellectual Property from Government Intrusion: Revisiting *SmithKline* and the Case for Just Compensation

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On October 2, 2000, the Supreme Court denied certiorari in literally hundreds of cases that accumulated over the preceding summer.<sup>1</sup> Among those passing quietly into the night was a petition from the Second Circuit in *SmithKline Beecham v. Watson Pharmaceuticals*,<sup>2</sup> where Chief Judge Winter held that copyright liability did not attach to a generic drug seller's use of a pioneer drug seller's copyrighted label.<sup>3</sup> The law clerk writing the certiorari pool memorandum likely discarded *SmithKline* as a fact-bound case, in an obscure area of copyright law in which there was no circuit split, authored by a highly respected circuit judge. Thus the Court never saw *SmithKline* for what it was: the latest monument to a judicially-led curtailing of intellectual property rights. Beginning with the Supreme Court's decision in *Florida Prepaid*,<sup>4</sup> the protection of intellectual property ("IP") has become all the more precarious – particularly where there is a government entity involved. Judicial hostility toward intellectual property rights is nothing new;<sup>5</sup> however, this latest wave comes after decades of legislative action to shore up protection of IP,<sup>6</sup> and at a time when such property rights are becoming increasingly central to innovation and the economy.<sup>7</sup> What is

1. See Supreme Court Order List (Oct. 2, 2000), available at <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/www.supremecourtus.gov/orders/courtorders/100200.pdf>.

2. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21 (2d Cir. 2000), cert. denied, 531 U.S. 872 (2000).

3. *Id.* at 29.

4. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999).

5. At one point, the "anti-patent" fervor of the Supreme Court prompted Justice Jackson, in a dissenting opinion, to remark that "the only patent that is valid is one which this Court has not been able to get its hands on." *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting). The story is also told that in pre-Supreme Court confirmation discussions with Senators, then-Judge Thurgood Marshall was asked about his views on patents. He reportedly responded, "I haven't given patents much thought, Senator, because I'm from the Second Circuit and as you know we don't uphold patents in the Second Circuit." Gerald J. Mossinghoff, *Side Bar: The Creation of the Federal Circuit*, in DONALD S. CHISUM, ET AL., *PRINCIPLES OF PATENT LAW* 29-30 (1998).

6. See, e.g., Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (April 2, 1982) (codified in part at 28 U.S.C. § 1295) (creating the United States Court of Appeals for the Federal Circuit); Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984) (codified in part at 21 U.S.C. § 355(j), 35 U.S.C. § 271(e)) ("Hatch-Waxman" Act); Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, 106 Stat. 4230 (Oct. 28, 1992) (codified in part at 35 U.S.C. §§ 271(h), 296(a)).

7. See, e.g., Kenneth Sutherland Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 *FOOD & DRUG L.J.* 453, 461-66 (1997) (relying on empirical data to show that patent law reforms and other changes in federal law have fueled the rise of biotechnology and biopharmaceutical industries); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 *U. CHI. L. REV.* 1017, 1018 (1989) (noting that the "biotechnology revolution has accelerated the commercial development of basic research"); Joshua Lerner, *Venture Capitalist and the Decision to Go Public*, 35 *J. FIN. ECON.* 293, 294 (1994); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *MGMT. SCI.* 173, 175 (1986) (finding that pharmaceutical firms' managers believed that sixty percent of all new products during 1981-82 would not have been developed without patent protection).

noteworthy about this newfound judicial skepticism toward claims of intellectual property protection is its direction in support of government actors at both the federal and state level. Although the Federal Circuit has adopted a pro-IP stance, resulting in more favorable rulings for patent owners, and greater damage awards as between private actors,<sup>8</sup> recent decisions from the Supreme Court and other circuits show these courts all too willing to sweep entire questions of infringement aside when there is a federal or state agency interest at stake.

This Article addresses this new curtailment of intellectual property rights in the name of government interests that has emerged at the turn of the millennium. Part I examines the *SmithKline* decision and the role Food and Drug Administration (“FDA”) policy played in shaping the outcome. Looking past the specifics of *SmithKline*, Part II takes a broader view at the interaction between IP rights and the administrative state. In particular, I focus on a small sampling of the ways in which the FDA and other federal agencies encumber or intrude upon, for better or for worse, one’s intellectual property. Part III offers a perspective on *SmithKline* as just the latest star in a constellation of recent decisions subjugating IP rights to federal and state government interests. Having diagnosed the current state of affairs, I then examine a potential remedy. Part IV considers a constitutional “takings” theory of infringement as a means of overcoming some of the recent judicially-created obstacles to protecting intellectual property from government use or interference. Thus, Part IV addresses one of the unanswered questions from *Florida Prepaid*: what currency does the Just Compensation Clause provide in questions of infringement?

## I. IT’S ONLY A LABEL: NEW LIMITS TO COPYRIGHT AFTER *SMITHKLINE*

Commercial labeling is the product of creative work in which the designer has a substantial investment and is generally copyrightable.<sup>9</sup> In the context of food, drugs and medical devices, such labeling is the subject of extensive regulation by the FDA.<sup>10</sup> FDA oversight is so rigorous that

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8. See Samuel Kortum & Josh Lerner, *Stronger Protection or Technological Revolution: What is Behind the Recent Surge in Patenting?*, NAT’L BUREAU OF ECON. RES. 8-9 (Working Paper No. 6204) (1997) (noting that in the eight years following the Federal Circuit’s creation, it had affirmed ninety percent of district court decisions holding patents to be valid and infringed, while reversing twenty-eight percent of decisions of invalidity or non-infringement). Similarly, as between private parties, the Supreme Court has upheld broad intellectual property rights. See, e.g., *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 122 S. Ct. 593 (2000) (affirming the Federal Circuit’s broad reading of the utility patent statute, 35 U.S.C. § 101).

9. See I M. NIMMER, *NIMMER ON COPYRIGHT* § 2.08[G], at 2-134 (“It is clear that [17 U.S.C. §] 102(a)(5) includes prints and labels used for articles of merchandise under the general protection accorded to pictorial, graphic and sculptural works.” (citing H.R. Rep. No. 94-1478, at 54 (1976)); *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 n.5 (2d Cir. 2000), *cert denied*, 531 U.S. 872 (2000).

10. See, e.g., 21 U.S.C. §§ 343 (2000) (food), 352 (2000) (drugs and medical devices); see also 21 U.S.C. § 362 (2000) (cosmetics).

Congress enacted a regime in 1984 to expedite the FDA's approval of "generic" versions of pharmaceuticals.<sup>11</sup> In order to qualify for expedited review, the generic drug must contain, among other things, "information to show that the *labeling* proposed for the new drug *is the same as the labeling approved for the listed [pioneer] drug . . .*"<sup>12</sup> This raises the question whether the generic drug manufacturer, who must use "the same labeling" as the pioneer drug, can be liable for copyright infringement if the pioneer has a copyright on his label. Recently in *SmithKline Beecham v. Watson Pharmaceuticals*,<sup>13</sup> the Second Circuit answered with an unequivocal "no."<sup>14</sup> In this Part, I consider whether the Second Circuit's decision was unnecessarily overbroad as a matter of law. SmithKline's copyright could have been afforded some protection while still effectuating the goals of the Hatch-Waxman Act. Further, the court could have exercised its equitable powers in a manner that would have protected both the interests of the copyright holder and the generic drug manufacturer. Instead, the *SmithKline* court simply swept away IP protection in deference to the FDA's administrative regime.

#### A. *Prelude to SmithKline*

SmithKline is the manufacturer of "Nicorette" nicotine chewing gum, an over-the-counter ("OTC") product designed to "help smokers overcome the cigarette habit."<sup>15</sup> Originally a prescription-only product, the FDA approved OTC sale of Nicorette on February 9, 1996.<sup>16</sup> To obtain approval for OTC sale of Nicorette, SmithKline submitted to the FDA various versions of a "user's guide and audiotape" that would accompany the product.<sup>17</sup>

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11. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984) (codified in part at 21 U.S.C. § 355(j), 35 U.S.C. § 271(e)) ("Hatch-Waxman" Act). Generic drugs are identical to pioneer drugs that have previously obtained FDA approval and can be marketed once the pioneer drug's patent and 21 U.S.C. § 355 exclusivity periods expire.

12. 21 U.S.C. § 355(j)(2)(A)(v) (2000) (emphasis added).

13. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21 (2d Cir. 2000), *cert. denied*, 531 U.S. 872 (2000).

14. *Id.* at 23.

15. *Id.*

16. *Id.*

17. *Id.* 21 U.S.C. § 355(b)(1)(F) (2000) requires applications for approval of a drug to include "specimens of the labeling proposed to be used for such drug." The Federal Food, Drug, and Cosmetic Act defines "label" and "labeling" for these purposes as "a display of written, printed or graphic matter upon the immediate container of any article" or "accompanying such article." 21 U.S.C. § 321(k), (m) (2000). The FDA has interpreted this provision to include "[b]rochures, booklets, . . . sound recordings, . . . and similar pieces of printed, audio, or visual matter descriptive of a drug. . . ." 21 C.F.R. § 202.1(i)(2) (2001).

Approximately “[seventy] changes” were made at the FDA’s request.<sup>18</sup> “The guide features graphics and drawings and the Tape features music and actors engaging in dialogue.”<sup>19</sup> They were the product of “several years and more than one million dollars” spent by SmithKline “developing a creative Guide and Tape that are an important part of the Nicorette product and an important component of the brand image that SmithKline has sought to create.”<sup>20</sup> Thus, after the FDA approved Nicorette and its accompanying labeling, SmithKline registered a federal copyright on the guide and audiotape script. Subsequently, the words and music on the tape were also registered.<sup>21</sup>

In 1999, after the expiration of SmithKline’s exclusivity period for Nicorette, Watson Pharmaceuticals received FDA approval to market a generic version of nicotine gum over-the-counter.<sup>22</sup> During Watson’s approval process, the FDA originally rejected the “proposed text for an audio tape [because it was] substantially different from the text of the SmithKline Tape.”<sup>23</sup> The FDA instructed Watson as follows: “The text for your proposed audio is not the same as that for the reference listed drug, Nicorette. . . . Please revise your tape text to be in accord with that of Nicorette.”<sup>24</sup> In response, Watson used a “verbatim” copy of SmithKline’s guide and tape to accompany its generic nicotine gum, and approval was granted.<sup>25</sup>

Before Watson could begin selling its product, SmithKline sued Watson, alleging willful copyright infringement of its guide and tape, and sought a preliminary injunction.<sup>26</sup> In determining whether to grant the preliminary injunction, the district court, per Judge Chin, relied on a letter it received from the FDA, in which the agency sought to “provide some context and clarify its position.”<sup>27</sup> The FDA explained that it had initially advised Watson that “the generic version of Nicorette had to have the same labeling,” but that later communications “clarified that position to address the concern that the Nicorette labeling might be subject to copyright protection.”<sup>28</sup> The FDA position was that “generic sponsors [of] smoking cessation aids, have discretion to design their own audio support

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18. *SmithKline*, 211 F.3d at 23.

19. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 63 F. Supp. 2d 467, 469 (S.D.N.Y. 1999).

20. *Id.* at 471.

21. *SmithKline*, 211 F.3d at 23.

22. *Id.*

23. *SmithKline*, 63 F. Supp. at 469.

24. *Id.*

25. *Id.* at 472.

26. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 23-24 (2d Cir. 2000), *cert. denied*, 531 U.S. 872 (2000).

27. *SmithKline*, 63 F. Supp. 2d at 470.

28. *Id.*

materials.”<sup>29</sup> The FDA claimed it “does not approve the specific words or approach taken” in “behavior support materials,” but rather that “it is the general concept of providing quitters with a variety of useful support materials that the [FDA] has required.”<sup>30</sup> The FDA also indicated it “had explained to Watson in a telephone conversation that ‘the “same labeling” requirement did not require that the generic’s behavioral support materials be *identical* to the innovator’s materials.’”<sup>31</sup> Relying on the FDA’s representations, Judge Chin rejected “Watson’s claim that it was forced by the FDA to copy the text of the SmithKline Guide and Tape verbatim” as a “gross exaggeration.”<sup>32</sup> He concluded that “[t]here are many different ways that a manufacturer can express the ideas used in SmithKline’s Guide and Tape, and Watson certainly could have proposed some different language . . . to avoid problems of copyright infringement.”<sup>33</sup> Examining the balance of harms, the district court granted SmithKline’s motion for a preliminary injunction.<sup>34</sup>

Subsequent to the issuance of the preliminary injunction, Watson revised its instructional materials to address the copyright concerns and submitted them to the FDA for its approval.<sup>35</sup> The FDA rejected the new guide, but advised Watson that it would approve a revised version of the allegedly infringing user’s guide.<sup>36</sup> Watson was provided with a marked-up copy of its allegedly infringing guide, in which the FDA indicated only a few bracketed words could be replaced.<sup>37</sup> The FDA thus determined that Watson “had to copy verbatim substantially all of the text used in the SmithKline Guide” and in the tape.<sup>38</sup> In response to a request from Judge Chin to “revisit” its decision, the FDA “decline[d] to change its approach to Watson’s labeling.”<sup>39</sup> It refused to “take copyright consideration into

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29. *Id.*

30. *Id.*

31. *Id.* (emphasis added).

32. *Id.* at 472.

33. *Id.*

34. *See id.* at 473.

35. SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc., No. 99 Civ. 9214, 1999 WL 1243894, \*3 (S.D.N.Y. Dec. 22, 1999).

36. *See id.*

37. *Id.* at \*3-4. For example, on the first page, the introductory words “SO YOU DECIDED TO QUIT! Congratulations!” could be replaced, as well as “Wallet Card” in the context of indicating where toll free numbers were printed in the user’s guide, but nothing else. *Id.* If we are to take the FDA seriously, presumably it would have refused to approve changing “Your decision to stop smoking is an important one,” *id.* at \*3, to “Your decision to stop smoking is important.”

38. *Id.* at \*4.

39. *Id.*



account . . . .”<sup>40</sup> Thus, given the FDA’s position, “it appear[ed to the district court] that Watson [could not] market its product without using instructional materials that are indeed identical in substantial respects to SmithKline’s copyrighted materials.”<sup>41</sup>

Facing this conundrum, Judge Chin chastised the FDA for refusing “now to take into account copyright considerations, when it has previously suggested that it ought to,” for flip-flopping in its position on Watson’s guide and tape, and for refusing “to acknowledge that the materials in this case are not just ‘labeling,’ but rather . . . instructional materials that do involve a certain amount of creativity.”<sup>42</sup>

[The FDA] refuses to permit Watson to express such basic concepts as “don’t be discouraged,” “quitting isn’t easy,” “it takes time,” and “the important thing is to try again until you succeed” in different words, when these same ideas could be expressed in a manner that would protect the public health without violating SmithKline’s copyrights. It surely has a duty to address the apparent conflict between the Copyright Act and the FFDCA [Federal Food, Drug, and Cosmetic Act].<sup>43</sup>

Despite this frustration, and mindful of the fact that the FDA was not a party to the action,<sup>44</sup> the district court concluded that it would be unjust “to continue to enjoin Watson . . . .”<sup>45</sup> Although he dissolved the injunction, Judge Chin also noted that SmithKline might still seek a “remedy [of] damages, in the nature of implied license fees, even though that remedy may not be an adequate one.”<sup>46</sup>

### *B. The SmithKline Decision*

The Second Circuit accepted an interlocutory appeal of the decision to dissolve the preliminary injunction, and with one important caveat, it affirmed. Writing for the panel, Chief Judge Winter held that “recognition of SmithKline’s claim here would severely undermine the Hatch-Waxman Amendments” and therefore directed “dismissal of SmithKline’s complaint for failure to state a claim.”<sup>47</sup>

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40. *Id.*

41. *Id.*

42. *Id.* at \*6.

43. *Id.*

44. *Id.* at \*6 n.3.

45. *Id.* at \*6.

46. *Id.* at \*7.

47. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000), *cert. denied*, 531 U.S. 872 (2000).

The court of appeals accepted that “SmithKline has demonstrated the existence of substantial issues under the copyright laws” and that “[a]bsent more, the propriety of a preliminary injunction would seem clear.”<sup>48</sup> It also rejected theories of non-infringement as a “fair use” or “implied license.”<sup>49</sup> However, the court concluded that the “Hatch-Waxman Amendments . . . not only permit but require producers of generic drugs to use the same labeling as was approved for, and is used in, the sale of the pioneer drug, even if that label has been copyrighted.”<sup>50</sup> Acknowledging that the “Copyright Act seems to prohibit such copying,” the court found “a conflict between two statutes.”<sup>51</sup> Chief Judge Winter concluded that “[i]f copyright law were to prevail, producers of generic drugs will always be delayed in – and quite often prohibited from – marketing the generic product, results at great odds with the purposes of the Hatch-Waxman Amendments.”<sup>52</sup> In contrast, there would be “[n]o such severe undermining of the purpose of the copyright laws” as “[t]he creation of the ‘labels to be approved by the FDA, such as the user’s guide and audio tape, is ancillary to the FDA’s administrative process.”<sup>53</sup> In Chief Judge Winter’s view, SmithKline simply did not need the protection of the copyright laws to have the incentive to create the guide and tapes.<sup>54</sup> Thus, the Second Circuit held that in enacting the Hatch-Waxman Amendment, Congress had trumped, or unknowingly amended, the copyright laws with respect to labels in the generic drug context.<sup>55</sup> Although the court limited its holding strictly to labels of “generic drug manufacturers who are required by the Hatch-Waxman Amendments to copy labeling,” its interpretation required the altogether dismissal of SmithKline’s complaint.<sup>56</sup>

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48. *Id.* at 25.

49. *Id.*

50. *Id.*

51. *Id.* at 27.

52. *Id.* at 28.

53. *Id.*

54. *See id.* at 29; cf. *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1345 (7th Cir. 1983) (Posner, J., concurring and dissenting) (“The balance tips against protection when the invention is the sort that was likely to be made, and as soon, even if no one could have patented it.”).

55. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000), *cert. denied*, 531 U.S. 872 (2000). Following the Supreme Court’s lead in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000), the court noted that “both time of enactment and specificity favor our interpretation,” as the Hatch-Waxman Act post-dated the Copyright Act of 1976, and “the Copyright Act’s broad generality contrasts with the Hatch-Waxman Amendments’ specific generic drug approval scheme.” *SmithKline*, 211 F.3d. at 28 n.3.

56. *Id.* at 29.

### C. Hard Cases Make Bad Law

*SmithKline* presents a difficult conflict between two statutory regimes arguably at odds with each other. One, the copyright laws, are aimed at “promot[ing] the Progress of Science . . . by securing for limited Times to Authors . . . the exclusive Right to their respective Writings.”<sup>57</sup> The other, the Hatch-Waxman Amendments, were intended to provide greater, and therefore cheaper, generic drug availability through expedited FDA approval: a goal effectuated by allowing generics to piggy-back on the work of pioneers. Copyright laws attack the free-rider problem; Hatch-Waxman arguably exacerbates it, though for laudable ends. But are these two regimes as necessarily in conflict as this dichotomy makes them out to be? Obviously, the court of appeals thought so. Perhaps Chief Judge Winter’s clean resolution – that the Hatch-Waxman Amendments trumped the copyright laws, thereby eliminating *SmithKline*’s claim of infringement – was too easy. It was not only overbroad, but in the long-run actually fails to effectuate the purpose of either statutory regime, purposes which are not in as sharp a conflict as the court would have us believe. At the root of the matter, however, was the court’s willingness to allow effective appropriation of *SmithKline*’s copyright, not by Watson Pharmaceuticals, but by the FDA.

#### 1. Overbreadth as a Matter of Law

The Second Circuit found a direct conflict between the copyright laws and the Hatch-Waxman Act based on its interpretation of “same” in section 355(j).<sup>58</sup> While conceding that “‘same’ may mean something less than ‘identical,’” the court concluded that “a legislative drafter would believe that a sameness requirement would lead to creation of works that would easily fall within the copyright law’s infringement test of ‘substantial similarity.’”<sup>59</sup> Of course, Congress had not foreseen the conflict posited by Chief Judge Winter,<sup>60</sup> and, if it had, it is doubtful that a legislator would have considered the intricacies of Second Circuit law. This “substantial similarity” test is a product of the Second Circuit, and in most cases is satisfied by an “‘ordinary observer test’ which queries whether an average lay observer would recognize the alleged copy as having been appropriated from the copyrighted work.”<sup>61</sup> It is a test well-suited to determining infringement of patterns and designs, but in the setting of regulated labels, it proves too much.

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57. U.S. CONST. art. I § 8 cl. 8.

58. 21 U.S.C. § 355(j)(2)(A)(v) (2000). See *SmithKline*, 211 F.3d at 26-27.

59. *SmithKline*, 211 F.3d at 27.

60. See *id.* at 29.

61. *Hamil Am., Inc., v. GFI, Inc.*, 193 F.3d 92, 100 (2d Cir. 1999).

The origins of the “substantial similarity” test can be found in *Bevan v. Columbia Broadcasting System, Inc.*,<sup>62</sup> where plaintiffs alleged that CBS had infringed their copyrighted play “Stalag 17” with the TV show “Hogan’s Heroes.”<sup>63</sup> The district court overturned a jury verdict on statutory copyright claims for the plaintiff because “[s]ubstantial similarity . . . is to be judged by comparison not of general ideas but of that which constitutes the author’s ‘expression.’”<sup>64</sup> Indeed, “Copyright is not infringed by an expression of the *idea* which is substantially similar where such similarity is necessary because the ideas or system being described is the same.”<sup>65</sup> The cases where the “substantial similarity” test has found the most currency, are unsurprisingly not those involving writings,<sup>66</sup> but rather those involving patterns and fabric designs, such as *Folio Impressions, Inc. v. Byer California*<sup>67</sup> and *Hamil America, Inc. v. GFI, Inc.*,<sup>68</sup> the latter being the case Chief Judge Winter cited. This is for the simple reason that *ideas* are not copyrightable, but specific collections of words or patterns are. Thus, Judge Tyler, who first articulated the “substantial similarity” test as such “doubt[ed] the validity and efficacy of the ‘audience’ or ‘lay observer’ rubric [of the substantially similar] test, except perhaps in *comparatively simple fields such as fabrics or clothing designs*. In the areas of . . . written works, this ‘test’ has the weakness of avoiding the serious analysis virtually required . . . .”<sup>69</sup>

Virtually every food or drug label, regardless of whether it is required to be the “same” by the Hatch-Waxman Act, would fail the “substantial similarity” test under Chief Judge Winter’s approach. Certainly, “familiar objects” enjoy only a narrow copyright.<sup>70</sup> This does not mean they enjoy no copyright, only that the bar for finding infringement is high. So one would expect it to be with FDA regulated labels – after all, they must all conform to certain FDA requirements, which alone would make them “substantially similar.” However, requiring the label of identical drugs to contain the

62. 329 F. Supp. 601 (S.D.N.Y. 1971).

63. *See id.* at 602.

64. *Id.* at 605.

65. *Baker v. Selden*, 101 U.S. 99 (1879) (emphasis added).

66. *See, e.g., Walker v. Time Life Films, Inc.*, 784 F.2d 44, 48 (2d Cir. 1986) (“The copyright protection granted to appellant’s book extends only to its particular expression of ideas, not to the ideas themselves, 17 U.S.C. § 102(b), a distinction easier to state than to apply.”). The court noted that “[i]n assessing claims of substantial similarity, courts therefore must decide ‘whether the similarities shared by the works are something more than mere generalized idea or themes[.]’” *Id.* at 48-49 (quoting *Warner Bros., Inc. v. Am. Broad. Co.*, 654 F.2d 204, 208 (2d Cir. 1981)).

67. 937 F.2d 759 (2d Cir. 1991) (involving fabric design pattern).

68. 193 F.3d 92 (2d Cir. 1999) (involving floral design used on fabric).

69. *Bevan*, 329 F. Supp. at 604 n.3 (emphasis added).

70. *Samara Bros., Inc. v. Wal-mart Stores, Inc.*, 165 F.3d 120, 132 (2d Cir. 1998).

“same” ideas is not tantamount to requiring that they be identical. The Hatch-Waxman Act requires the latter, not the former. Indeed, leaving the world of Second Circuit case law, we discover that other courts recognize that some copyright infringement requires “verbatim or near-verbatim copying.”<sup>71</sup> Indeed, the Seventh Circuit in *Alberto-Culver*, per then-Judge Stevens, resolved a conflict involving labels on female deodorants by holding that the general descriptive claims of a product were not copyrightable.<sup>72</sup> The court rejected arguments that the defendant infringed in making substantially similar claims.<sup>73</sup> Courts interpreting *Alberto-Culver* have taken it to mean that if “fact-based works are involved, ‘substantial similarity’ generally exists only where there has been a verbatim or near-verbatim copying.”<sup>74</sup> Thus where the alleged infringer “expresses many of the same ideas . . . but it alters the precise language[,] in doing so [it] avoids infringement.” As one court noted:

Perhaps the same result might not have followed comparably modest changes to the text of a play or other work of fiction. But where as here an author’s options are limited by the need to present the same facts and to describe identical processes, all that can reasonably be expected is that he or she avoid the parroting or near-parroting of the earlier language. [The defendant] did that, and copyright law requires nothing more.<sup>75</sup>

Thus, the test for infringing a label required by the Hatch-Waxman Act, as with all labels, could be that of identity.<sup>76</sup> As “same” may be interpreted as something less than “identical,” copyright holders such as SmithKline, who put tremendous time and resources into developing creative supplementary materials, would be protected against direct verbatim copying.

## 2. Between a Rock and a Hard Place or Aligning Purposes?

The response to the argument advocating findings of infringement where the materials are identical is that it would be contrary to the purposes of the Hatch-Waxman Act. Hatch-Waxman was intended to expedite approval of generic drugs with the end goal being to provide the American

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71. *Sassafras Enters., Inc. v. Roshco, Inc.*, 889 F. Supp. 343 (N.D. Ill. 1995).

72. *Alberto-Culver Co. v. Andrea Dumon, Inc.*, 466 F.2d 705, 711 (7th Cir. 1972) (Stevens, J.).

73. *Id.*

74. *Sassafras*, 889 F. Supp. at 347.

75. *Id.*

76. The Second Circuit dismissed this argument in a footnote, deferring to the FDA’s interpretation of the Hatch-Waxman Act as requiring the “manufacturers of generic drugs to copy the labeling of pioneer drugs ‘near-verbatim.’” *SmithKline*, 211 F.3d at 27 n.2. The reasonableness of this deference will be explored in Part I.C.4, *infra*.

consumer with a greater variety of pharmaceuticals at a lower cost. Requiring a generic drug company to develop its own labeling for approval slows the process, and thus, the “same,” even perhaps “identical” labeling is required. Therefore, the copyright of the label must give way to the generic’s use. This is all efficient, because “the profit sought by the creator of the pioneer drug label flows primarily from the administrative approval of the drug and the patent and exclusivity periods,” thus, it is “simply not conceivable that . . . pioneer drug producers will so fear the copying of labels by future generic drug producers that some . . . will lack the incentive to create labeling needed for FDA approval.”<sup>77</sup>

Chief Judge Winter’s reasoning recognizes that copyright law “treads a difficult and often tenuous line” between promoting and restricting expression and innovation.<sup>78</sup> As Lord Mansfield put it:

We must take care to guard against two extremes equally prejudicial; the one that men of ability, who have employed their time for the service of the community may not be deprived of their just merits and reward for their ingenuity and labor; the other that the world may not be deprived of improvements nor the progress of the arts be retarded.<sup>79</sup>

However, the end goal of the Hatch-Waxman Act – more, cheaper drugs – is no different from the end goal of intellectual property law. That is, granting a limited monopoly creates the incentive to innovate and develop, and thus over the long-run provides society with greater goods to choose among.<sup>80</sup>

Therefore, rather than reading the copyright laws as effectively repealed by the Hatch-Waxman Act in this case, the court of appeals should have found a way to satisfy both (i.e., by applying the verbatim standard). This is particularly true given that the Supreme Court counsels against reading even minor repeals by implication.<sup>81</sup> Where such an interpretation is required, the

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77. *Id.* at 29.

78. *Bevan*, 329 F. Supp. at 604.

79. *Sayre v. Moore*, 102 Eng. Rep. 139, 140 (1785), *quoted in Bevan*, 329 F. Supp. At 605.

80. *See Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975) (“[T]he ultimate aim is, by this incentive to stimulate artistic creativity for the general public good.”); *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (“The economic philosophy behind the [copyright] clause . . . is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare . . .”).

81. *See, e.g., Watt v. Alaska*, 451 U.S. 259, 267 (1981) (noting that courts must read two federal statutes “to give effect to each if [it] can do so while preserving their sense and purpose.”); *Northwest Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284 (1985) (examining the Court’s decision in *Silver v. NYSE*, 373 U.S. 341 (1964) and discussing the maxim

court is to “narrow[] only to the extent necessary to effectuate [the conflicting] policy.”<sup>82</sup> True, Chief Judge Winter’s opinion limits the effect of the Hatch-Waxman Act to a generic’s labels, rather than broader advertising.<sup>83</sup> Even so, he reached further than was necessary to resolve the case. By concluding that Hatch-Waxman allows *identical* copying, generics are now free to lift every word, every graphic, and even the very music used by the pioneer in its tapes. Changes that the district court found to be important in dissolving the injunction would no longer be necessary.<sup>84</sup> Under the Second Circuit’s rule, generics are free to copy with impunity. The court exacerbates the “free rider” problem that copyright laws were intended to address.

Over the long-run, we cannot even take solace in the notion that society is at least benefiting from the more rapidly available, less expensive drugs. Pioneer drug manufacturers will still seek to recover the costs of research, development, and approval – including the labeling costs – but they will now have to recover them over a shorter time frame. Thus, as a simple matter of economics, where labeling costs are high, the cost of the pioneer drug will rise.<sup>85</sup> As a monopolist, the rational pioneer will price its drug

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disfavoring repeals by implication).

82. *Northwest Wholesale*, 472 U.S. at 292.

83. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000), *cert. denied*, 531 U.S. 872 (2000).

We emphasize that we do not read the Hatch-Waxman Amendments to repeal other rights under the Copyright Act of copyright owners in SmithKline’s circumstances. Even though such an owner cannot enforce its copyright against generic drug manufacturers who are required by the Hatch-Waxman Amendments to copy labeling and who do no more than that, it still retains a copyright, if otherwise valid, in the label and might well pursue copyright claims against potential infringers in other circumstances, e.g., use of the copyrighted material in non-labeling advertisements.

*Id.* at 29.

84. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214, 1999 WL 1243894, at \*5 (S.D.N.Y. Dec. 22, 1999). Judge Chin noted,

[T]he revised materials are now significantly more different from SmithKline’s materials. For example, the user guide features a new layout and graphics and is designed as a package insert rather than as a booklet. Watson represents that the music and actors on the audio taper are different, and the transcript of the audio tape shows that the instructions are presented in a different format and factual setting.

*Id.*

85. It should be frankly acknowledged that in most cases the labeling costs are practically insignificant to the costs of research and development. It is the rare case, such as *SmithKline*, where a manufacturer will have spent in excess of “one million dollars” developing labeling such as the “Guide and Tape, in a process spanning several years.” *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 63 F. Supp. 2d 467, 469 (S.D.N.Y. 1999). Additionally,

[T]he profit sought by the creator of the pioneer drug labels flows primarily from the administrative approval of the drug and the patent and exclusivity periods free from competition that follow. . . . It is simply not conceivable that, if we reject SmithKline’s claim, pioneer drug products will so fear the copying of labels by future generic drug products that some pioneer products—or even one of them—will lack the incentive to create labeling needed for FDA approval.

*SmithKline*, 211 F.3d at 29. Of course, it is only the rare case that should be of concern to us, for

where marginal cost equals marginal revenue.<sup>86</sup> As it is no longer able to spread the costs of label development over the life of the drug, but instead must recoup those costs during the exclusivity period (as the free-riding competitor will not have those development costs), the pioneer must raise the price of the pioneer drug. Thus, in most cases, marginal cost will equal marginal revenue at a higher price and lower quantity of production.<sup>87</sup> The result is detrimental to the consumer for the life of the pioneer's monopoly. This negative outcome does not end once the generics enter the market. The generic manufacturers are not philanthropists, but rather profit maximizers. To the extent that they are able to capitalize on monopoly profits, they will. There are not an infinite number of generic drug manufacturers, and thus we will expect to see oligopolistic behavior.<sup>88</sup> While generics will be able to undercut the pioneers, and must do so in order to gain original market share, eventually prices will stabilize – and if they are starting at a higher price, they will likely stop at a higher price. The pioneer will not be able to cut prices as aggressively as it now has proportionately higher average costs than the generic, in the amount of the cost of developing the label.

Once the generics enter the market, pioneers will now face competition from their own work in label development, where generics free ride on the years and millions of dollars spent developing creative labeling.<sup>89</sup> As the district court originally noted, the guide and tape “are an important part of the Nicorette product and an important component of the brand image that SmithKline has sought to create. The introduction into the market of virtually identical user guides and instructional tapes is likely to confuse consumers and threaten consumer goodwill.”<sup>90</sup> The net result is a disincentive for pioneer drug manufacturers to invest anything more than the bare minimum FDA requires in their labeling. This effect is acutely felt in the OTC market where it is brand name and brand image that the pioneer must rely on to distinguish it from the generic version. Thus, while it is undoubtedly true that the *SmithKline* decision will not create a “lack [of]

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only then is a copyright of the labeling likely to be in dispute.

86. See generally W. KIP VISCUSI, ET AL, *ECONOMICS OF REGULATION AND ANTITRUST* ch. 4 (2d ed. 1995).

87. See *id.* at 77.

88. See PHILIP AREEDA & LOUIS KAPLOW, *ANTITRUST ANALYSIS* 252-263 (5th ed. 1997). This behavior, of course, depends on the number of generic drug manufacturers of a particular drug. The larger the number, the less likely we would expect to see oligopolistic behavior. See *id.*

89. SmithKline provided affidavits in which the company claimed that it “spent more than one million dollars developing the Guide and Tape,” *SmithKline*, 63 F. Supp. 2d at 469, and that it “spent in excess of \$200 million in bringing Nicorette to market and developing a brand image.” *Id.* at 472.

90. *Id.* at 471.



incentive to create labeling needed for FDA approval,”<sup>91</sup> it will reduce the incentive to make labeling an integral part of marketing and investment. Brand image will be divorced from anything a competitor may copy at will, and the research and study that went into designing layouts, formats, settings, and music will but cut to a minimum. The net effect is a less effective product for the end user, because the interests of the pioneer manufacturer in developing effective marketing materials and the FDA in approving effective products are no longer congruent.

### 3. An Equitable Way Out?

The *SmithKline* decision creates an all or nothing situation: either it is copyright infringement and therefore the Hatch-Waxman regime is stillborn; or the Hatch-Waxman Act preempts the copyright statute and the plaintiff has no claim. Yet our choices need not be so stark. At the district court, Judge Chin recognized that there was potentially a third way out, though procedurally it was not the proper time for him to explore it. He noted that even if SmithKline were correct in its “interpretation as to the interplay between the Copyright Act and the [Federal Food, Drug, and Cosmetic Act], a court of equity is not likely to find that the public should be deprived of the alternative of a generic version of Nicorette,” and therefore no injunctive relief would be granted.<sup>92</sup> However, he noted that SmithKline might still have a damages remedy “in the nature of implied license fees.”<sup>93</sup> Thus, prior to the Second Circuit’s eviscerating SmithKline’s cause of action, a court exercising its equitable powers could have awarded a reasonable royalty to SmithKline for the use of its copyright.

The awarding of a reasonable royalty or licensing fee for infringement of intellectual property is hardly a novel concept.<sup>94</sup> Such a remedy is

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91. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000), *cert. denied*, 521 U.S. 872 (2000).

92. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214, 1999 WL 1243894, at \*7 (S.D.N.Y. Dec. 22, 1999).

93. *Id.*

94. For example, as will be discussed in Part II, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the disclosure of registration data submitted by the pioneer manufacturer and allows subsequent use by “me too” manufacturers. 7 U.S.C. §136a(c)(1)(D) (2000). Such “me too” registrants may be required to compensate the pioneer for the use of the data. *See* 40 C.F.R. pt. 152 E (2000). Taking the licensing concept to the extreme, some scholars advocate completely replacing our current intellectual property rights regime with a “reward system” in which the state offers “rewards to creators of information” and such information is then “made available to all who want it” for a fee. STEVEN SHAVELL, *PRINCIPLES OF ECONOMIC ANALYSIS OF LAW* ch. 12, at 12-18 (2000) (unpublished manuscript). Professor Shavell argues that like the property rights system “the reward system encourages production of information because the creator of information obtains a benefit from so doing. But unlike the property rights system, the reward system results in optimal dissemination of information because the information is in the public domain; anyone can use it.” *Id.*

explicitly recognized in the patent and copyright laws.<sup>95</sup> In patent law, such a “reasonable royalty” is assessed by considering the “royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty,”<sup>96</sup> as well as a “hypothetical negotiation” between a willing licensor and a willing licensee.<sup>97</sup> Although the Seventh Circuit has endorsed the “hypothetical negotiation” approach in copyright infringement,<sup>98</sup> the Second Circuit has rejected it.<sup>99</sup> Thus, we see a hesitance by the Second Circuit to engage in such judicial discretion that was echoed by Chief Judge Winter in *SmithKline*. He rejected “fair use” and “implied license” theories in part because “[i]f either were to prevail, some new law, essentially judge-made, would have to be fashioned.”<sup>100</sup> Instead, he found more compelling “straightforward ground that the Hatch-Waxman Amendments . . . require producers of generic drugs to use the same labeling,” thus trumping the copyright laws.<sup>101</sup> This ruling did preclude the need for the court to exercise its equitable powers and fashion a remedy or “some new law”; however it can hardly be said that it was an act of judicial minimalism. This is particularly ironic given the pervasiveness of the use of the “reasonable royalty” alternative in the copyright context.

Although the Copyright Act only specifies injunctive remedies,<sup>102</sup> actual damages,<sup>103</sup> profits of the infringer,<sup>104</sup> or statutory damages,<sup>105</sup> courts may exercise their equitable powers and award a “reasonable royalty” while declining to issue an injunction.<sup>106</sup> Quoting Professor Nimmer’s influential treatise on copyright, the Ninth Circuit observed that “where great public injury would be worked by an injunction, the courts might . . . award damages or a continuing royalty instead of an injunction in such special

95. See 35 U.S.C. § 284 (2000) (“Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer . . .”); 17 U.S.C. §§ 111 (2000) (compulsory license for not-for-profit broadcast relays), 115 (2000) (compulsory license allowing musicians and record companies to make and sell their own recordings of copyrighted musical works (“cover” license)), 119 (2000) (compulsory license for satellite transmission to “unserved households”).

96. *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

97. *Id.*

98. See *Deltak, Inc. v. Advanced Sys., Inc.*, 767 F.2d 357, 362 n.3 (7th Cir. 1985).

99. See *Bus. Trends Analysts, Inc. v. Fredonia Group, Inc.*, 887 F.2d 399, 405 (2d Cir. 1989).

100. *SmithKline*, 211 F.3d at 25.

101. *Id.*

102. 17 U.S.C. § 502 (2000).

103. *Id.* § 504.

104. *Id.*

105. *Id.*

106. See, e.g., *Abend v. MCA, Inc.*, 863 F.2d 1465, 1479 (9th Cir. 1988).

circumstances.”<sup>107</sup> Similarly, the reasonable royalty is the only relief available in a suit for patent or copyright infringement against the United States or contractors “acting for the Government and with the authorization or consent of the Government . . . .”<sup>108</sup> No injunctive relief may be sought.<sup>109</sup> The “public injury” exception endorsed by the Ninth Circuit, and the denial of injunctive relief in suits against the United States both are founded on the recognition that in some circumstances a greater societal good is served by allowing infringement. Yet, in these circumstances, the property right of the IP owner is not ignored: it is compensated with a royalty. As Judge Chin recognized, *SmithKline* was ripe for similar treatment. Watson would be able to use the “same” label as SmithKline, while SmithKline would not go uncompensated. Thus, granting an “implied license” to Watson would have effectuated the Hatch-Waxman Act goal of expediting FDA review and simultaneously preserved the value of SmithKline’s copyright by preventing free-riding. Such financial compensation would at least help to bring SmithKline’s interest in developing the guide and tape back into alignment with the FDA approval process. The short and long-term public interest is served, and the purpose of both legislative regimes is met. Of course, such a contorted license/royalty treatment would not be necessary but for the FDA’s refusal to consider copyright in applying the Hatch-Waxman Act to generic drug applications.

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107. *Abend*, 863 F.2d at 1479 (quoting 3 M. NIMMER, NIMMER ON COPYRIGHT § 14.06[B] at 14-56.2 (1988) (internal quotations omitted)); *Deltak*, 767 F.2d at 362-64. *But see BTA*, 887 F.2d at 405.

108. 28 U.S.C. § 1498(b) (2000) (“[T]he exclusive remedy of the owner of such copyright shall be by action against the United States in the Court of Federal Claims for the recovery of his reasonable and entire compensation as damages for such infringement, including the minimum statutory damages . . .”).

109. *Cf. Pitcairn v. United States*, 547 F.2d 1106, 1118 n.13 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978) (“We refer to the fact that a patentee cannot obtain an injunction against a government-supplier or government-contractor and is confined, for his exclusive remedy, to a suit for ‘reasonable and entire compensation’ (i.e., monetary compensation) against the United States under 28 U.S.C. § 1498.”). The Federal Circuit recently addressed this issue in *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1571-72 (Fed. Cir. 1996), *judgment vacated*, 520 U.S. 1183 (1997), *aff’d*, 140 F.3d 1470 (1998):

The government’s unlicensed use of a patented invention is properly viewed as a taking of property under the Fifth Amendment through the government’s exercise of its power of eminent domain and the patent holder’s remedy for such use is prescribed by 28 U.S.C. § 1498(a). . . . Under section 1498(a), the patent owner is entitled to its “reasonable and entire compensation for such use and manufacture.” Because recovery is based on eminent domain, the proper measure is “what the owner has lost, not what the taker has gained. . . .” Generally, the preferred manner of reasonably and entirely compensating the patent owner is to require the government to pay a reasonable royalty for its license as well as damages for its delay in paying the royalty.

#### 4. The Real Culprit: The FDA

The *SmithKline* decision represented judicial capitulation by the court of appeals to the FDA at the expense of SmithKline's intellectual property rights. However, it did not come before the district court expressed its frustration with the FDA. Judge Chin lamented the FDA's taking "varying, inconsistent positions on whether Watson's instructional materials must be identical to SmithKline's materials."<sup>110</sup> He lambasted the FDA for violating its "duty to address the apparent conflict between the Copyright Act and the FDCA,"<sup>111</sup> and noted that he was "tempted" to rule "that the FDA must take [SmithKline's] copyrights into account."<sup>112</sup> In the end, he refrained because of the procedural posture of the case – the FDA was not a party to the action.<sup>113</sup> Likewise it was procedural posture that would tee up SmithKline's claim for the Second Circuit to dismiss. *SmithKline* came to the court of appeals as an interlocutory appeal of the dissolving of a preliminary injunction. In balancing the harms and the public interest at the preliminary injunction stage, the district court was forced to reject SmithKline's argument that Watson assert a claim against the FDA under the Administrative Procedure Act or some other administrative remedy, though it noted that "[s]uch a claim might have merit, as the FDA's conduct in this case has indeed been perplexing."<sup>114</sup> Thus, although the district court concluded "SmithKline has demonstrated irreparable harm and the existence of sufficiently serious issues going to the merits to make them a fair ground for litigation,"<sup>115</sup> it recognized "[i]n view of the FDA's position," that "no generic version of Nicorette is likely to reach the market anytime soon, unless SmithKline's arguments are rejected."<sup>116</sup>

In defense of the FDA, the flip-flops, although "perplexing," are not incomprehensible. Clearly, the FDA was working its way through new territory at the intersection of the Hatch-Waxman Act and the copyright laws, at the end of the process settling on a clear, easy-to-administer rule requiring use of nearly identical language in the generic's label. Such a rule would certainly expedite review of labels in conformance with the objectives of the Hatch-Waxman Act. Yet, surely Judge Chin was correct when he said, "it is difficult to understand how the FDA can simply ignore the

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110. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214, 1999 WL 1243894, at \*2 (S.D.N.Y. Dec. 22, 1999).

111. *Id.* at \*6.

112. *Id.* at \*6 n.3.

113. *See id.*

114. *Id.*

115. *Id.* at \*5.

116. *Id.* at \*7 (emphasis added).

public's interest in the protection of copyrights, and I would think that it is within the FDA's mandate to address the interplay between the Copyright Act and the FFDCA."<sup>117</sup> It is not enough for the FDA to simply hide behind some notion of the public interest without taking into account all aspects thereof.<sup>118</sup> Thus, we must consider why the FDA insisted on interpreting the Hatch-Waxman Act as it did, and whether such an interpretation would have survived a direct, rather than collateral challenge.

A generic drug manufacturer wishing to produce a pioneer's drug must submit an abbreviated new drug application ("ANDA") to the FDA.<sup>119</sup> Among other things the ANDA must include "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [pioneer] drug"<sup>120</sup> as well as "information to show that the labeling proposed for the new drug is the same as the labeling approved for the [pioneer] drug."<sup>121</sup> However, the FDA may not require the ANDA applicant to include "information in addition to that [statutorily] required."<sup>122</sup> If the generic applicant meets the ANDA requirements in section 355, then the FDA is required to approve the application,<sup>123</sup> and is expected to do so within one hundred eighty days.<sup>124</sup> Thus, the FDA has a short period of time to determine whether "information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the [pioneer] drug,"<sup>125</sup> which it must do while determining that the active ingredients,<sup>126</sup> route of administration and dosage,<sup>127</sup> and bioequivalence,<sup>128</sup> are the same. Obviously, it is in the FDA's interest to simplify the review, and requiring identical labels does just that. Examining different individual labels on a case-by-case basis, without a bright-line test for "sameness" is costly.<sup>129</sup> The verbatim approach has the benefit of being

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117. *Id.* at \*6 n.3.

118. Indeed this very issue was litigated in the context of "public health" and the use of cost/benefit analysis by the Environmental Protection Agency. *See* Brief for Cross-Petitioners, *Am. Trucking Ass'ns, Inc. v. Browner*, 530 U.S. 1202 (2000) (No. 99-1426), available at 2000 WL 1014021. Cross-Petitioners argued that cost/benefit analysis is inherent in the very concept of "public health," and thus it is erroneous for EPA to refuse to consider anything outside of health effects in promulgating rules under the Clean Air Act. *See id.* However, in the context of the statutory language of the Clean Air Act in dispute, the Supreme Court rejected this argument. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

119. *See* 21 U.S.C. § 355(j) (2000).

120. *Id.* § 355(j)(2)(A)(i).

121. *Id.* § 355(j)(2)(A)(v).

122. *Id.* § 355(j)(2)(A).

123. *See id.* § 355(j)(3).

124. *See id.* § 355(j)(4)(A).

125. *Id.* § 355(j)(3)(G).

126. *See id.* § 355(j)(3)(C).

127. *See id.* § 355(j)(3)(D).

128. *See id.* § 355(j)(3)(F).

129. *Cf.* PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD & DRUG LAW* 1045 (2d ed. 1991).

even-handed and actually simplifies the process for the ANDA applicant – it just may come at the expense of the pioneer’s copyright.<sup>130</sup> If the FDA took a less restrictive stance where a copyright existed, it potentially opened the door to challenges from generics seeking changes to labels even in the absence of a copyright issue.

The FDA’s desire for simplification is surely reasonable, but that does not mean that its interpretation of “same” in the labeling context is. In fact, FDA’s original position recognized the “concern that [such] labeling might be subject to copyright protection,”<sup>131</sup> thus advising that “the ‘same labeling’ requirement did not require that the generic’s behavioral support materials be identical to the innovator’s materials.”<sup>132</sup> Why then the change in position?

The FDA claimed that it would not take copyright considerations into account because it “ha[d] never been directed by Congress to consider potential copyright rights in approving generic drug labeling.”<sup>133</sup> However, that is akin to it saying it simply did not *want* to consider copyrights. Perhaps the FDA was emboldened to take this aggressive position because it essentially had a free pass in the *SmithKline* case. As it was not a party to the case, there was little chance of FDA being bound by an unfavorable court decision. Further, as it was not a direct review of the FDA’s policy, the agency was not required to give a rationale – it just had to act. FDA reasonably gambled that Watson would not resort to a direct challenge, hoping instead to have its policy de facto approved by a district court strapped with limited options. Given the procedural posture – a preliminary injunction – FDA was likely to get its way (as in fact it did). What FDA likely did not anticipate was the added bonus of the Second Circuit’s

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(“[L]itigation on a case-by-case basis [] is an inadequate method of regulation. It fails to inform the regulated industry of its obligations, it involves . . . delay, and the end results are often uncertain. Worst of all, it inevitably results in invidious selective enforcement . . .”) [hereinafter HUTT & MERRILL]. See also *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645 (1973) (recognizing that “a case by case approach is inherently unfair”).

130. As the Second Circuit noted, “the administrative process of approving a new label would . . . drain the resources of the FDA and generic producer,” particularly if “labels that were ‘substantially similar’ to copyrighted labels on pioneer drugs had to be avoided. . . .” *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 28 (2d Cir. 2000), *cert. denied*, 521 U.S. 872 (2000).

131. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 63 F. Supp. 2d 467, 470 (S.D.N.Y. 1999).

132. *Id.* (quoting FDA letter to the district court).

133. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214 1999 WL 1243894, at \*4 (S.D.N.Y. Dec. 22, 1999) (quoting FDA letter to the district court).

interpretation of Hatch-Waxman as trumping the copyright laws. Chief Judge Winter's opinion is as much or more than the FDA could have hoped for had its interpretation been reviewed under *Chevron*<sup>134</sup> analysis.

Suppose the FDA's interpretation of the Hatch-Waxman Act had been directly challenged – how would the FDA have fared? Such a challenge would have been reviewed under *Chevron*'s two-step analysis. Step one asks “whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”<sup>135</sup> The second step, if “Congress has not directly addressed the precise question at issue,” is to determine “whether the agency's answer is based on a permissible construction of the statute,” i.e., is the agency interpretation reasonable?<sup>136</sup> The Second Circuit's decision in *SmithKline* does not predispose an answer to these questions. Such a direct challenge to agency interpretation would not have been made under the duress imposed by the FDA in *SmithKline*, where if the copyright laws were not put aside, the generic drug could not be marketed. As FDA would be a party, it would be required to interpret the Act in a manner consistent with the reviewing court's judgment. If the deck had not been stacked, who is to say that the Second Circuit might not have been predisposed differently?<sup>137</sup> But more importantly, the reviewing court applying *Chevron*, (unlike the *SmithKline* opinion, which turns on de novo interpretation of the Hatch-Waxman Act by the court of appeals), would have to squarely consider (1) did Congress address this precise issue?, and (2) is the FDA interpretation reasonable?

Obviously, Congress did not consider the meaning of “same . . . labeling” against the backdrop of the copyright laws.<sup>138</sup> The *SmithKline* opinion concedes that Congress had not “foreseen the statutory conflict exposed by the present action.”<sup>139</sup> Thus, the question remaining under *Chevron* step two is whether the FDA's interpretation is a “permissible” or “reasonable” one. As one influential commentator has noted:

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134. *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843-44 (1984). Where the intent of Congress is not clear, courts uphold the FDA's “permissible” and “reasonable” interpretation of the statute. See, e.g., *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974 (1986) (relying on *Chevron* in deferring to FDA's interpretation of the Federal Food, Drug, & Cosmetic Act).

135. *Chevron*, 467 U.S. at 842-43.

136. *Id.* at 843.

137. At the district court level, Judge Chin's opinion clearly suggested that he would have favored an interpretation that at least accounted for the copyright laws. See *SmithKline*, 1999 WL 1243894, at \*6.

138. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000), cert. denied, 531 U.S. 872 (2000).

139. *Id.* at 29.

[T]he fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the Food and Drug Administration exerting initiative and leadership in the public interest. [T]he Food and Drug Administration is obligated to develop whatever innovative and creative regulatory programs are reasonable and are most appropriate to achieve the fundamental objectives laid down by Congress.<sup>140</sup>

Thus, while we must consider whether FDA's interpretation reasonably effectuates the goals of the Hatch-Waxman Act, it seems, as Judge Chin suggested, that we must temper this with FDA's obligation to effectuate the copyright laws in the "public interest" as well.<sup>141</sup> In other words, the proper inquiry is not a reasonable interpretation of the Hatch-Waxman Act in the abstract, but in light of the Copyright Act.

Originally, FDA thought that "the same . . . labeling requirement" was not particularly rigorous with aids and supplementary material as the agency claimed it "does not approve the specific words or approach taken. Rather, it is the more general concept of providing . . . a variety of useful support materials that the [FDA] has required."<sup>142</sup> Prior to the enactment of the Hatch-Waxman regime, the bottleneck for the approval of generic drugs was the requirement of a full "New Drug Application" for post-1962 new drugs, which entailed providing detailed safety and effectiveness information (including human testing), even if it was identical to that of the pioneer drug.<sup>143</sup> The data accompanying the pioneer drug "constituted confidential commercial information that was not disclosable to the public or available for use by another applicant . . ."<sup>144</sup> It was these costly and laborious investigations by the generic manufacture and the accompanying FDA approval that the Hatch-Waxman Act sought to by-pass.<sup>145</sup> The various requirements for ANDAs established by the Hatch-Waxman Act, including the "same . . . labeling," are to ensure that, in short-circuiting the full new drug approval process, public health is not compromised. Thus, it is crucial

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140. Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177 (1973), reprinted in HUTT & MERRILL, *supra* note 129, at 1041-42.

141. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.* No. 99 Civ. 9214 1999 WL 1243894, at \*6 (S.D.N.Y. Dec. 22, 1999).

142. *Id.* at \*2.

143. See HUTT & MERRILL, *supra* note 129, at 484.

144. *Id.*

145. See H.R. Rep. No. 98-857, at pt. 2 (August 1, 1984), reprinted in 1984 U.S.C.A.N. 2686, 2688 ("Secretary Califano urged Congress to act for three reasons: (1) The exclusion of generics was anti-competitive; (2) the requirements of duplicative tests on humans unnecessarily endangered human health; and (3) the approval process diluted the resources of the FDA.").



that the generic drug actually be the same as the previously approved pioneer and used in the same manner. Labeling is obviously crucial to use.<sup>146</sup> Presumably, in most cases, the label could be copied directly – as most labels, containing only a description of the product, would not even be copyrightable.<sup>147</sup> However, where there is a copyright, one would think that the FDA would be obligated to protect the “public interest” in copyrights, and therefore provide guidance on how to reasonably avoid infringement – guidance like that provided to Watson before FDA changed positions to require near verbatim copying. Such guidance certainly would not be binding on the copyright holder, who would still be free to sue for infringement, but it would provide the reviewing court with a reasoned approach (something FDA failed to do in *SmithKline*) that accommodates both the intellectual property rights and the purpose of the Hatch-Waxman regime.

This approach is not foreign to FDA, which would not give away confidential safety and effectiveness data until mandated to do so by Congress.<sup>148</sup> With this history of protecting private rights, it is, if anything, a surprise that FDA would be so willing to ride roughshod over copyright protection. Just as FDA did not give away confidential data without congressional authorization, so too it should not have staked out a position effectively requiring copyrighted labels be given away without direction from Congress. Far from supporting the FDA’s position, the Agency’s acknowledgment that it “ha[d] never been directed by Congress to consider potential copyright rights in approving generic drug labeling,”<sup>149</sup> cuts against an interpretation that altogether trumps copyright protection. In the Hatch-Waxman Act, Congress developed an elaborate system that cut into some aspects of patent protection.<sup>150</sup> Had Congress intended to curb or particularly eliminate copyright protection, it knew how to tell FDA.

In the rare case of a valid copyright, how much trouble is it for FDA to review similar, though not identical guidance material? While any review comes at some cost, surely the bottleneck in Watson’s generic drug approval would have been science-heavy inquiries such as confirmation of the

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146. Cf. *SmithKline*, 1999 WL 1243894, at \*6 n.2.

147. See, e.g., *Alberto-Culver Co. v. Andrea Dumon, Inc.*, 466 F.2d 705, 711 (7th Cir. 1972).

148. See HUTT & MERRILL, *supra* note 129, at 484. However, once it received this mandate from Congress, the FDA became zealous in making data available for public disclosure. See *infra* Part II.C.

149. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 24 (2d Cir. 2000), *cert. denied*, 531 U.S. 872 (2000).

150. 21 U.S.C. § 355(j)(2)(A)(vii) (2000) (requiring generic certification that the pioneer: (I) has no patent; (II) has an expired patent; (III) has a patent that will expire before the generic is approved; or (IV) has an invalid patent or a patent that will not be infringed by the generic’s use); 35 U.S.C. § 271(e) (2000) (overruling *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), by making experimental use of a patented drug for FDA approval a noninfringing act; defining generic certification that the pioneer has an invalid patent or a patent that will not be infringed by the generic’s use as an act of patent infringement).

bioequivalence, rather than determining if Watson had adequately “express[ed] such basic concepts as ‘don’t be discouraged,’ ‘quitting isn’t easy,’ ‘it takes time,’ and ‘the important thing is to try again until you succeed’ in different words, when these same ideas could be expressed in a manner that would protect the public health without violating SmithKline’s copyrights.”<sup>151</sup> Although there may be cases where protecting public health would require identical labeling, it is reasonable to believe in those cases the label would not be copyrightable in the first instance.<sup>152</sup> In *SmithKline*, far from saying the copyright was invalid, the Second Circuit went out of its way to “emphasize” that SmithKline “still retains a copyright, if otherwise valid, in the label and might well pursue copyright claims against potential infringers in other circumstances . . . .”<sup>153</sup> In sum, the FDA’s interpretation of the Hatch-Waxman Act is not a reasonable one, as its own vacillation on the matter demonstrates.

This brings us to the final point about a hypothetical direct review of the FDA’s interpretation. A reviewing court would be struck by the “varying, inconsistent positions” taken by the FDA.<sup>154</sup> As Judge Chin observed, “The FDA’s conduct in this case has indeed been perplexing. It shifted its position in a manner that has prejudiced Watson. It refuses now to take into account copyright consideration, when it has previously suggested that it ought to take copyrights considerations into account.”<sup>155</sup> Such flip-flopping would result in significantly less deference to the FDA. Although it is true that the Supreme Court “has rejected the argument that an agency’s interpretation ‘is not entitled to deference because it represents a sharp break with prior interpretations’ of the statute in question,”<sup>156</sup> such a change must be “amply justified”<sup>157</sup> with a “reasoned analysis.”<sup>158</sup> Moreover, an “agency interpretation of a relevant provision that conflicts with the agency’s earlier interpretation is entitled to considerably less deference than a consistently

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151. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214 1999 WL 1243894, at \*6 (S.D.N.Y. Dec. 22, 1999).

152. *Cf. Alberto-Culver Co. v. Andrea Dumon, Inc.*, 466 F.2d 705, 711 (7th Cir. 1972) (Stevens, J.); *Sassafras Enters., Inc. v. Roshco, Inc.*, 889 F. Supp. 343, 348 (N.D. Ill. 1995) (“[I]t would be a relief if manufacturers of deodorants, cooking utensils, and other products would stop claiming copyright protection for the descriptive components of their labels, pamphlets and other instructional materials. Nine times out of ten copyright law will not protect that sort of literature . . .”).

153. *SmithKline*, 211 F.3d at 29.

154. *SmithKline*, 1999 WL 1243894, at \*2.

155. *Id.* at \*6.

156. *Rust v. Sullivan*, 500 U.S. 173, 186 (1991) (quoting *Chevron*, 467 U.S. at 862).

157. *Id.* at 187.

158. *Motor Vehicle Mfrs. Assn. of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

held agency view.”<sup>159</sup> In sum, “the consistency of an agency’s position is a factor in assessing the weight that position is due.”<sup>160</sup> The FDA’s position in *SmithKline* was anything but consistent. To support its position, FDA must come forward with more than hortatory statements about the public interest, the lack of congressional mandates, and minor administrative inconvenience. Short of demonstrating that a contrary interpretation would shut down generic drug approval, probably FDA would not have prevailed. A reviewing court seeking to reconcile the Hatch-Waxman Act and copyright laws would reject FDA’s interpretation as an illegitimate attempt to essentially appropriate SmithKline’s copyright.

Ultimately, FDA’s position should be seen for what it is – nothing short of an appropriation of copyrighted labels. Under an interpretation where Hatch-Waxman trumps the copyright laws, it is FDA, through its NDA approval power, rather than the copyright holder who would “license” the copyrighted label and supplementary materials for use by generics, with no benefit to the copyright holder. Certainly, there are many legitimate circumstances where FDA may limit or restrict the use of intellectual property by its owner. However, we should be more skeptical of those situations in which FDA can be said to have appropriated that intellectual property. In Part II, we will explore the limitations on intellectual property rights imposed by the FDA and its organic statute, and to a lesser extent other administrative agencies, distinguishing between cases of restriction and appropriation, and inquiring into the legitimacy of these limitations.

## II. INTELLECTUAL PROPERTY AT THE MERCY OF THE ADMINISTRATIVE STATE

If the FDA’s decisions leading up to *SmithKline* were isolated examples of agency power to limit and restrict intellectual property rights, then one should ask, “What’s the big deal?” However, the FDA’s effective appropriation of copyrighted labels in the ANDA context is but the tip of the iceberg. Congress has given broad authority to the FDA and other federal agencies in a number of settings to appropriate data, formulations, and other intellectual property from the developers and to provide this information to competitors.<sup>161</sup> Similarly agencies have taken it upon themselves to unilaterally disclose intellectual assets under certain circumstances.<sup>162</sup> In

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159. *INS v. Cardoza-Fonseca*, 480 U.S. 421 n.30 (1987) (internal quotations omitted).

160. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993).

161. *See, e.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984) (codified in part at 21 U.S.C. § 355(j) (2000), 35 U.S.C. § 271(e) (2000)) (“Hatch-Waxman” Act); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(c)(1)(D) (2000).

162. *See, e.g.*, Peter Barton Hutt, *Public Information and Public Participation in the Food and Drug Administration*, 36 Q. BULL. ASS’N FOOD & DRUG OFFICIALS 212 (1972), reprinted in HUTT & MERRILL, *supra* note 129, at 1299-1300 [hereinafter Hutt, *Public Information*]; 21 C.F.R. §§

some cases, the FDA has claimed the authority to regulate assets, such as trade names, out of existence altogether.<sup>163</sup> It is not the purpose of this Article to catalog all of the areas where the FDA, much less other administrative agencies, compromise the intellectual property of those it is charged with regulating. Rather, this Part seeks only to demonstrate that such impingement (if not infringement) is pervasive in the modern administrative state – particularly in the FDA.

### A. *The Hatch-Waxman Regime*

In the patent context, the most widely heralded legislative regime to limit and redistribute patent protection is the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>164</sup> commonly known as the Hatch-Waxman Act. The Act created a regulatory mechanism to reduce the delay in FDA approval of generic versions of drugs already approved for market.<sup>165</sup> If it can be shown that “the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed] drug,”<sup>166</sup> the new drug applicant need only file an Abbreviated New Drug Application (“ANDA”). The Act delineates the requirements for an ANDA and effectively exempts an ANDA applicant from having to perform the exhaustive clinical studies required for a standard new drug application. Instead, the applicant need only show, for example, that the “bioequivalen[ce],” “labeling,” “route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug”<sup>167</sup> to obtain FDA approval. However, the generic drug company is not just allowed to use the patented drug company’s drug and supporting data – it is allowed to do this *before* the patent has expired. Actions now held exempt from infringement under 35 U.S.C. section

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20.61 (2001) (new drug applications), 812.38 (2001) (medical devices), 514.11 (2001) (animal drugs).

163. See, e.g., Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1041–42 (Jan. 6, 2000) (codified at 21 C.F.R. Part 101) (suggesting that the FDA could “prohibit the use of specific terms that now appear in product names, trademarks, trade names, symbols and company logos”) [hereinafter *Dietary Supplements Regulations*]; *United States v. 70½ Dozen Bottles*, and *76½ Dozen Bottles of “666,”* Civ. No. 112, 114 (M.D. Ga. 1945) (Deaver, J., instructing the jury), reprinted in VINCENT A. KLEINFELD & CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT JUDICIAL AND ADMINISTRATIVE RECORD 1938-1949*, at 89 [hereinafter *U.S. v. 70½ Dozen Bottles “666”*].

164. Pub. L. 98-417, 98 Stat. 1585 (1984) (codified in part at 21 U.S.C. § 301, 35 U.S.C. § 271(e) (2000)).

165. See 21 U.S.C. § 355(j) (2000).

166. *Id.* § 355(j)(2)(A)(i).

167. *Id.* § 355(j)(2)(A)(iii) – (v).

271(e)(1) were held to have infringed a valid patent under section 271(a) prior to Hatch-Waxman.<sup>168</sup> The Act prevents “[p]atent litigation . . . until after the generic manufacturer has at least demonstrated a legitimate interest in a drug by investment in preparing a complete ANDA.”<sup>169</sup> The bill created a moratorium on suits for experimental use that could have been brought under *Roche Products, Inc. v. Bolar Pharmaceutical, Inc.*,<sup>170</sup> pursuant to section 271(a), until after the competitor files an ANDA.

The patent holder is not left without any recourse because the ANDA applicant must make one of four certifications as to the status of any patent “which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval.”<sup>171</sup> Three of these certifications—that there is no patent, that any relevant patents have expired, or simply asking for approval contingent upon the expiration of the patent—raise no special issues, as there would have been no patent infringement prior to the Hatch-Waxman Act.<sup>172</sup> It is the final certification, the so-called paragraph IV certification, “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted,”<sup>173</sup> that invokes the amended patent laws. If the patent *is valid* or *will* be infringed by such manufacture, use, or sale, then filing the certification is itself an act of patent infringement under section 271(e).<sup>174</sup> Thus, patent infringement in an ANDA case is distinct from other types of patent infringement and is defined separately from other acts in infringement in 35 U.S.C. section 271.<sup>175</sup> The Federal Circuit has held that filing a paragraph IV certification is enough to give patentees the right to sue the applicant under section 271(e).<sup>176</sup> An ANDA applicant is subject to suit for patent infringement merely by filing a paragraph IV certification: the applicant need not make, use, or offer to sell or sell any patented invention.<sup>177</sup>

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168. See *Roche Prods., Inc. v. Bolar Pharms. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

169. H.R. REP. NO. 98-857, pt. 2, at 61 (1984).

170. 733 F.2d 858 (Fed. Cir. 1984).

171. 21 U.S.C. § 355(j)(2)(A)(vii) (2000).

172. See *id.* § 355(j)(2)(A)(vii)(I) – (III).

173. *Id.* § 355(j)(2)(A)(vii)(IV).

174. 35 U.S.C. § 271(e)(2)(A) (2000) (emphasis added). Section 271(e)(2)(A) provides:  
It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act[, codified at 21 U.S.C. § 355(j),] or described in section [355(b)(2)] of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

*Id.*

175. *Id.*

176. See *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (“[S]ection 271(e)(2) provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity.”).

177. See *id.*

Prior to the Hatch-Waxman Act, “if the generic obtains approval and goes on the market before the patent expires, then the patent holder can sue for patent infringement.”<sup>178</sup> In contrast, now

The provisions of the bill . . . modify this rule by providing that if a generic files for approval and requested marketing authority during the life of the patent that the FDA cannot act immediately. . . . The generic must also notify the patent holder. The patent holder must then commence litigation within forty-five days to assert the validity of the patent [in order to obtain a thirty-month injunction against FDA approval].<sup>179</sup>

Thus, the Hatch-Waxman Act gives the patent-holder a right to a thirty-month injunction preventing FDA approval of a generic that arguably infringes. However, the patentee lost the right to sue someone using their patented drug for research and other uses “reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.”<sup>180</sup>

The proponents of the Hatch-Waxman Act urged its adoption “as the best possible compromise between two competing economic interests.”<sup>181</sup> In addition to the ANDA provisions, the Act also provided for “patent term extension,”<sup>182</sup> this increasing the life of the patent beyond seventeen years – particularly for those patent holders whose marketing of their patented product had been held up by FDA approval. Despite this “exchange of property interests”<sup>183</sup> it is clear that patent holders have lost significant rights to competitors through the Hatch-Waxman regime.

As one court noted, “Congress made a fully self-conscious choice between two directly competing interests: continuing full protection and the rights of patent holders, on the one hand, and on the other, assuring access by the public to medically beneficial new products at truly competitive market prices (i.e., lower prices) . . .”<sup>184</sup> That court concluded that “[i]n essence, Congress elevated the health care interests of the public above the pecuniary interests of the patent holders.”<sup>185</sup> Certainly, as a matter of public policy, promoting public health is a laudable goal, but it should be frankly

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178. H.R. REP. NO. 98-857, pt. 2, at 9 (1984).

179. *Id.*

180. 35 U.S.C. § 271(e)(1) (2000).

181. H.R. REP. NO. 98-857, pt. 2, at 7 (1984).

182. 35 U.S.C. §§ 154-156 (2000).

183. H.R. REP. NO. 98-857, pt. 2, at n.20 (1984).

184. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1276 (N.D. Cal. 1991).

185. *Id.* at 1276-77.

recognized that in this case it came at a cost to IP rights, which itself creates social costs. The *Intermedics* court acknowledged the negative impacts on patent holders:

Congress reduced the scope of the rights of patent holders in two significant respects. First it permitted potential competitors, during the life of the patent, to engage in acts that otherwise clearly would constitute acts of infringement, as long as those acts generated data the FDA would use in deciding whether to approve a product for the commercial marketplace. Since Congress knew that the FDA sometimes required data based on considerable use of a product, Congress knew that creating this protection would deprive patent holders of sales that might well be significant . . . . The second negative impact on the interests of patent holders that Congress effected through the adoption of § 271(e)(1) was arguably even more significant. Under the scenarios that would have [been] obtained under *Roche*, a competitor could not have begun generating data for the FDA until after the expiration of the patent [thus effectively adding] several years of life to patents by making it impossible for competitors to be ready to enter the commercial marketplace in any significant measure for several years after the formal expiration of the patent holder's rights.<sup>186</sup>

Thus, courts acknowledge that Congress made “hard choices” in enacting the Hatch-Waxman regime.<sup>187</sup>

In accepting these “hard choices,” courts have also gone on to give section 271(e)(1) an especially broad reading. For example, as interpreted by the Supreme Court, the Hatch-Waxman Act infringement exception applies not just to individual provisions of federal law regulating “drug-related inventions,” but rather to the entirety of any federal law, including the FDCA, at least some of whose provisions regulate drugs.<sup>188</sup> In determining that Congress “used the word ‘law’ in its broader sense,” the Court found that section 271(e)(1) also applies to medical devices that are subject to FDA approval.<sup>189</sup> Further, lower courts interpreting *Eli Lilly* and applying the section 271(e)(1) exception have held that it is not lost just because some of the non-infringing uses (i.e. those reasonably related to gaining FDA approval to market) also double as “uses” that fall outside those permitted by the statute.<sup>190</sup> There has been a “reluctance to conclude that Congress intended the courts, when construing [section 271(e)(1)] to

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186. *Id.* at 1277.

187. *Id.*

188. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665-66 (1990).

189. *Id.* at 667.

190. *See Intermedics*, 775 F. Supp. at 1278-79.

ascribe much (or any) significance either to the indirect (ripple) effects of a defendant's otherwise infringing activities, or to inferences about 'purposes'" in engaging in certain conduct.<sup>191</sup> Thus interpreted, the Hatch-Waxman Act's infringement exception can grow beyond a mere experimental use exception.<sup>192</sup> Indeed, there has been slippage for patent-holders' rights. For example, the *Intermedics* court suggested, "[P]otential competitors foreseeably must engage in considerable 'business' development and promotion activity just to meet the FDA's requirements."<sup>193</sup> So long as any acts can be "reasonably related to the development and submission of information' to the FDA," additional business purposes are disregarded and there is no infringement.<sup>194</sup> Taking this approach to its logical conclusion, the *Intermedics* court determined that trade show demonstrations of an allegedly infringing medical device were not acts of infringement because a "reasonable trier of fact would be compelled to conclude that at least some of [the alleged infringer's] demonstration activity was reasonably related to identifying potential clinical investigators and, therefore, to generating data for submission to the FDA."<sup>195</sup> This "House-that-Jack-built" approach to the section 271(e)(1) exception threatens to balloon a limited exception into a loophole for generic manufacturers to effectively begin marketing products and to secure future market share even before a patent has expired. Although expanding the Hatch-Waxman infringement exception may ultimately be good for the consumer, it must be acknowledged that it cheapens the intellectual property rights of the pioneer developer.

### B. Required Disclosure

The patent and copyright laws are not the only regimes under which the owner of an intellectual asset is required to disclose the contents of that asset. What makes them unique is that in exchange for disclosure, the owner receives the federally-protected right to exclusivity (including the right to license or not to license) over the asset. However, there are other regimes employed by the FDA and Environmental Protection Agency ("EPA") under which the asset owner must disclose and *lose* the exclusive rights to the asset

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191. *Id.* at 1279.

192. For a discussion of an experimental use exception to the pre-*Roche* and pre-Hatch-Waxman patent laws, see Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357, 360 (1957).

193. *Intermedics*, 775 F. Supp. at 1279.

194. *Id.* at 1280.

195. *Id.* at 1287.



in order to be allowed to use the asset. Thus, these innovations are not only left unprotected, they are actually affirmatively revealed to competitors. In some cases there is compensation for competitors' use, but in others, the only compensation is the privilege of using the innovation.

One such regime is the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA").<sup>196</sup> FIFRA requires premarket approval ("registration") of all pesticides distributed or sold in the United States.<sup>197</sup> Such registration data must be disclosed by the pioneer manufacturer to EPA for use by subsequent generic (or "me too") manufacturers.<sup>198</sup> The pioneer has no discretion in who may subsequently use its data. Nonetheless, in *some* instances the "me too" manufacturer must compensate the originator of the use of the data.<sup>199</sup> Indeed, when there are disputes over data compensation they may be subject to compulsory arbitration.<sup>200</sup> An original data submitter who refuses to participate in an arbitration proceeding forfeits the right to compensation.<sup>201</sup> Nonetheless, the "me too" applicant is only required to pay "reasonable compensation for producing the test data to be relied upon,"<sup>202</sup> rather than full compensation for the competitive injury flowing from disclosure.<sup>203</sup>

There are limits to the data which EPA is allowed to disclose under FIFRA. Although Congress intended to provide consumers and competing pesticide manufacturers access to scientific data in the 1972 amendments to FIFRA,<sup>204</sup> it originally excluded trade secrets from public disclosure.<sup>205</sup> Thus, while the act provided for "mandatory licensing" of some test data, it excluded data that would fall under the trade secrets act.<sup>206</sup> The pioneer could mark that data it believed to be a trade secret, and the EPA was to determine what information contains or relates to trade secrets.<sup>207</sup> If the EPA proposed to release data which a registrant believes to be protected, the registrant "may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection . . ."<sup>208</sup> Factors that the EPA was to consider included: "(1) the cost of developing the data;" (2) the competitive advantage provided by the data; "(3) the extent to which the data are not independently known or

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196. 7 U.S.C. § 136 (2000).

197. *Id.*

198. *Id.* §136a(c)(1)(D).

199. 40 C.F.R. § 152E (2001).

200. 29 C.F.R. § 1440 (2001).

201. *Chevron Chem. Co. v. Costle*, 499 F. Supp. 732, 736 (D. Del. 1980) [hereinafter *Chevron Chemical II*].

202. 7 U.S.C. § 136a(c)(1)(D) (1994).

203. *Chevron Chem. Co. v. Costle*, 443 F. Supp. 1024, 1031 (N.D. Cal. 1978) (internal citation omitted) [hereinafter *Chevron Chemical I*].

204. Federal Environmental Pesticide Control Act, Pub. L. 92-516, 86 Stat. 973 (Oct. 21, 1972).

205. *Chevron Chemical I*, 443 F. Supp. at 1028-29.

206. Trade Secrets Act, 18 U.S.C. § 552; see *Chevron Chemical I*, 443 F. Supp. at 1029.

207. See *Chevron Chemical I*, 443 F. Supp. at 1029.

208. *Id.*

available to others; and (4) the extent to which the owner has maintained their confidentiality.”<sup>209</sup> However, after several series of amendments FIFRA was again amended in 1978 to eliminate the prohibition against EPA considering data classified as trade secrets.<sup>210</sup> Data submitted after September 30, 1978 was given a ten-year period of exclusive use, in which the EPA could not consider that data in conjunction with a “me too” applicant.<sup>211</sup> Following the ten years of exclusivity, there is a five-year window in which the originator is compensated for use of the data.<sup>212</sup> Data submitted after December 31, 1969 (but prior to September 20, 1978) was given a fifteen-year window in which it could be used without permission, but only if there was reasonable compensation.<sup>213</sup> As it currently stands, the FIFRA regime provides new registrants with a ten-year window of exclusivity, after which they have no protection for data which might be considered trade secrets and which could still provide a competitive advantage.

The FDA also oversees regimes in which there is no effective compensation for disclosure. For example, food additives<sup>214</sup> and color additives,<sup>215</sup> are subject to public regulations, rather than private licenses, and “thus permit any person to engage in their manufacture.”<sup>216</sup> In these areas of public regulation under which any firm can market its own product the FDA reasoned that scientific data provided by applicants provided no competitive advantage and could be disclosed to the public immediately upon promulgation of the regulation.<sup>217</sup> Because the FDA essentially promulgates definitions of food and color additives when it approves or “lists” them, those firms that pioneer new additives are unable to sustain any competitive advantage. Their new additive must be made public in order for it to even be marketed.<sup>218</sup>

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209. *Id.* at 1031 (citing RESTATEMENT OF TORTS § 757 (trade secrets)).

210. Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. 95-396, 92 Stat. 820 (Sept. 30, 1978); see also *Chevron Chemical II*, 499 F. Supp. at 735.

211. 7 U.S.C. § 136a(c)(1)(D)(i) (2000).

212. *Id.*

213. *Id.* § 136a(c)(1)(D)(ii). The FIFRA regime was challenged as a taking of property without just compensation, and as a taking for private use rather than for public use, both in violation of the Fifth Amendment. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). The challenge was partially successful for a limited set of claims, but left the FIFRA framework in place. *Id.* Takings claims as a means of protecting intellectual property rights and the *Ruckelshaus* case will be discussed in Part IV, *infra*.

214. 21 U.S.C. § 348 (2000).

215. 21 U.S.C. § 376 (2000).

216. Hutt, *Public Information*, *supra* note 162, at 1300.

217. HUTT & MERRILL, *supra* note 129, at 1301.

218. Until 1997 antibiotics were treated the same way. 21 U.S.C. § 357 (1994), *repealed by* The

### C. Unilateral Disclosure

In addition to products subject to public regulations, the FDA makes vast quantities of privately generated data available pursuant to the Freedom of Information Act (“FOIA”).<sup>219</sup> As former FDA Chief Counsel Peter Hutt observed in proposing FDA’s public information regulations in 1972:

The Food and Drug Administration is the largest repository of private scientific research in the world. [It] receive[s] mountains of important data and information on the safety, effectiveness, and functionality of foods and drugs, and undoubtedly will soon be receiving the same type of information for devices and cosmetics, that is available nowhere else. Since 1938, virtually none of it has been divulged. It is now proposed, however, that most of it will become available for public disclosure upon request.<sup>220</sup>

The FDA’s original public information regulations were implemented in 1972, and have been subsequently amended.<sup>221</sup> What made the FDA’s decision controversial was concern that there were inadequate safeguards to protect the confidentiality of information that genuinely could be regarded as trade secrets, such that disclosure would harm the competitive advantage of the data provider. One difficulty is, of course, defining “trade secret.”<sup>222</sup> FDA’s definition of “trade secrets and commercial or financial information” relies on the *Restatement (Second) of Torts*.<sup>223</sup> The D.C. Circuit defined trade secret as “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of

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Food and Drug Administration Modernization Act of 1997, § 125 (1997). Under section 125 of the Modernization Act, antibiotics are now subject to the New Drug Application requirements of 21 U.S.C. § 355, that apply generally to new drugs. *Id.*

219. 5 U.S.C. § 552 (2000).

220. Hutt, *Public Information*, *supra* note 162, at 1300. As adopted, the policy of the FDA is to “make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.” 21 C.F.R. § 20.20(a) (2000).

221. 37 Fed. Reg. 9128 (May 5, 1972) (codified as amended in 21 C.F.R. pt. 20).

222. *See, e.g., Zotos Int’l, Inc. v. Young*, 830 F.2d 350 (D.C. Cir 1987); *Zotos Int’l, Inc. v. Kennedy*, 460 F. Supp. 268 (D.D.C. 1978).

223. 21 C.F.R. § 20.61 (2000) stating:

(a) A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one’s business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one’s business and is of a type customarily held in strict confidence and regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.)

*Id.* Data and information submitted or divulged to the FDA “which fall within the definitions of a trade secret or confidential or financial information are not available for public disclosure.” *Id.* § 20.61(c).

trade commodities and that can be said to be the end product of either innovation or substantial effort.<sup>224</sup>

FDA's broad approach to data disclosure, set out in 21 C.F.R. Part 20, raises concerns that even trade secrets may be disclosed within the "mountains" of non-confidential data. Unlike other agencies that reluctantly acknowledged some FOIA access rights to submitted data, FDA designed and imposed a system "in which access is the norm and confidential status the exception."<sup>225</sup> This presumption of access makes it even more likely that trade secrets may fall into the hands of competitors, despite FDA's commitment to protect trade secrets and other confidential information from public disclosure.<sup>226</sup> As one commentator observed, the "role of FDA's career officials in handling FOIA matters unfortunately has involved a history of antagonism toward the views of commercial submitters of confidential data. Because so much of the data submitted to the NDA review process is valuable, industry has pressed repeatedly for better protection and better systems for accounting for confidential research data . . . ."<sup>227</sup> The FDA position has historically (since the 1970's) been one of viewing disclosure as the "preferred outcome of disputes about information on new drugs."<sup>228</sup> Although FDA provides for exemptions from disclosure for trade secrets and other confidential information, FDA has made the "policy choice" to stop companies from claiming trade secret status for case reports and data summaries, and has obtained legal victories supporting this pro-disclosure stance.<sup>229</sup>

In some instances, the only recourse available to a data owner is to sue the FDA to prevent disclosure. To prevail, the challenger must show that FDA acted arbitrarily in its decision to disclose the data, a high standard to meet.<sup>230</sup> However, first the data owner must be aware of intended disclosure. Prior to 1989 there was no requirement that data owners be informed of *all* releases. Nonetheless, where data had been marked confidential, but the FDA determined "the confidentiality of data or information is uncertain," the

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224. Pub. Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

225. James T. O'Reilly, *Implications of International Drug Approval Systems on Confidentiality of Business Secrets in the U.S. Pharmaceutical Industry*, 53 FOOD & DRUG L.J. 123, 128 (1998).

226. *Id.*

227. *Id.*

228. *Id.* at 129; see also Gary Yingling, *Veterinary Drugs: The Impact of the Laws of Confidentiality on International Communications*, 38 FOOD DRUG COSM. L.J. 35 (1983).

229. See Pub. Citizen Health, 704 F.2d at 1281; Anderson v. Dep't of Health and Human Servs., 907 F.2d 936 (10th Cir. 1990). The exemptions are laid out in 21 C.F.R. Part 20.D. A person may designate part or all of the information in submitted records as exempt. See 21 C.F.R. § 20.61(d) (2001).

230. See Chrysler Corp. v. Brown, 441 U.S. 281 (1979). Those objecting to disclosure are permitted to bring suit pursuant as explained in 21 C.F.R. § 20.46 (2001).

FDA would “consult with the person who has submitted or divulged the data.”<sup>231</sup> In those circumstances where the FDA rejects the request for confidentiality the data owner is given five days to institute suit in federal district court—and if she does file suit, “the [FDA] will not disclose the records involved until the matter and all related appeals have been concluded.”<sup>232</sup> Moreover, where the data submitter has marked information as confidential and the FDA receives a request for that data, the agency “will make reasonable efforts to notify the submitter,” who has five working days from receipt of notice to object to disclosure.<sup>233</sup> If the requesting party then sues for disclosure under the FOIA, the FDA will notify the data submitter, who may intervene.

The Pharmaceutical Manufacturers Association sought to require the FDA to “provide notice to an affected drug company of *any proposed release* of information” pursuant to FOIA “in order to provide an opportunity for the affected company to consult with the FDA concerning the propriety of the release of said information, and to provide an opportunity for judicial review of the FDA’s decision.”<sup>234</sup> However, the D.C. federal district court rejected the argument that the “FDA must notify the drug companies of the proposed release of *any and all* information which they submitted or which concerns them before it is actually released.”<sup>235</sup> Pre-disclosure notification was only finally required after the first President Bush signed an executive order that ordered federal agencies to inform companies of the agency’s intent to disclose *prior to* actual disclosure.<sup>236</sup> One critic of the FDA’s disclosure policies urges giving even “more notice to industrial submitters”<sup>237</sup> and suggests that the FDA take a more receptive approach to requests for confidential handling and prior notification before release of information.<sup>238</sup> In the meantime, protection of trade secrets in data reported to the FDA largely remains at the discretion of the agency, though within the parameters its has set out in 21 C.F.R. Part 20.

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231. 21 C.F.R. § 20.45 (2001).

232. *Id.* § 20.46.

233. *Id.* § 20.61.

234. *Pharms. Mfr. Ass’n v. Weinberger*, 401 F. Supp. 444, 445 (D.D.C. 1975) (emphasis added).

235. *Id.* at 447 (emphasis added). The court reasoned: “If there is no right to nondisclosure under the F.O.I.A., the Court does not perceive how there could be a right, under the F.O.I.A., to notice before a decision regarding nondisclosure is made.” *Id.* at 448.

236. Exec. Order No. 12,600, 52 Fed. Reg. 23,781 (Feb. 25, 1989).

237. See O’Reilly, *supra* note 225, at 131.

238. See *id.* FDA has expressed “antipathy” to presubmission requests for confidential handling. See *id.*; 21 C.F.R. § 20.44 (2000) (“No [presubmission] request . . . shall be accepted if the status of the records involved is already determined by § 20.111 or by any other regulation [in part 20]”); *id.* § 20.111 (allowing for public disclosure of certain data and information submitted voluntarily to the FDA); *Carson Prods., Co. v. Califano*, 594 F.2d 453 (5th Cir. 1979).

*D. IP Regulated Away*

The FDA's administrative actions with respect to intellectual property have not been limited to appropriation and dissemination. The FDA has the authority to regulate many intellectual assets effectively out of use. Certainly there is nothing novel about a regulatory agency imposing limits on one's intellectual asset. The patent grant, for example, does not give the right to *make* or *use* one's invention, but merely to *exclude* others from using it.<sup>239</sup> The Federal Food, Drug, and Cosmetic Act requires that new drugs, patented or otherwise, be approved for use by the FDA prior to "introduction into interstate commerce."<sup>240</sup> Thus, to suggest that the FDA can effectively prevent manufacturers from using or profiting from their intellectual property is wholly unremarkable. What *is* remarkable is the breadth of IP over which the FDA at least purports to exercise regulatory authority.

In conjunction with its authority to regulate labeling claims,<sup>241</sup> the FDA purports to be empowered to regulate or prohibit the "use of specific terms that now appear in product names, trademarks, trade names, symbols, and company logos . . ."<sup>242</sup> In the case of dietary supplements<sup>243</sup> the FDA position, based on 21 U.S.C. § 343(r)(6), is that if manufacturers "wish to continue using trademarks and trade names that imply a disease claim, they may do so, provided that they first meet the safety and efficacy standards and other regulatory requirements applicable to drugs or, in appropriate cases, provided that they obtain authorization to make a health claim."<sup>244</sup> However, it is worth noting that the FDA emphasized that this regulation

239. See CHISUM, ET. AL., PRINCIPLES OF PATENT LAW 2-5 (1998).

240. 21 U.S.C. § 355 (2000).

241. *Id.* §§ 343 ("Misbranded food"), 352 ("Misbranded drugs and devices"), 362 ("Misbranded cosmetics").

242. *Dietary Supplements Regulations*, supra note 163, at 1041.

243. The battles over regulation of dietary supplements were ultimately taken to Capitol Hill where the FDA suffered an embarrassing defeat. Congress enacted the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which "created a new regime for the regulation of dietary supplements." *Id.* These products had previously been regulated either as foods or as drugs – those for which a health related claim was made were regulated as drugs. The DSHEA effectively carved dietary supplements out from drugs and left them only subject to FDA's general oversight of foods. See 21 U.S.C. §§ 321(g)(1), 343(r)(6), 343-2 (2000). A dietary supplement manufacturer who wished to make a statement permitted under § 343(r)(6) need not obtain prior review of the statement. The statement need only be truthful and not misleading, and must include a disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." *Dietary Supplements Regulations*, supra note 163, at 1001-02. However, if the dietary supplement manufacturer includes a claim that is related to disease (i.e., a claim to diagnose, cure, mitigate, treat, or prevent disease), then the supplement requires prior approval as a drug or prior authorization for a health claim.

244. *Dietary Supplements Regulations*, supra note 163, at 1042.

would not disadvantage some manufacturers over others.<sup>245</sup> “[R]ather, all manufacturers will be precluded from using trademarks and trade names that contain an implied disease claim unless they have obtained new drug approval or health claim authorization. Thus, manufacturers will not suffer any competitive injury.”<sup>246</sup> Nonetheless, FDA can have a say in restricting the name of one’s product—no matter the investment and marketing that may have previously gone into that name or the good will that may be associated with it.

FDA’s willingness to restrict the use of trademarked names is not newfound. In 1945, federal prosecutors seized several dozen bottles of the product “666,” manufactured by the Monticello Drug Company on the ground that it was misbranded.<sup>247</sup> The product was misbranded because its “name, appearance, cartons, etc., created in the minds of purchasers the impression that the article was the product which had formerly sold as a treatment for malaria and had contained quinine, whereas the article no longer contained quinine.”<sup>248</sup> The jury was charged to consider whether an average member of the buying public would be misled by the product’s packaging, color, and name, into believing that the new product had the attributes of the old.<sup>249</sup> Thus, if the average consumer would believe the product still contained quinine and thus had the properties of the old product, it would be misbranded as a drug. The jury returned a verdict for the government, and judgment was entered condemning the product.<sup>250</sup>

What is interesting to note about the “666” case is what was *not* at stake. The judge was quick to instruct the jury that the “666” trademark was not itself being attacked. “[C]ertainly the old product of 666, when [World War II] is over and the ingredients can be obtained for that product, can be manufactured and again put on the market for people with malaria . . . .”<sup>251</sup> The restriction on the trademark was merely its *use on a different product*, rather than an outright prohibition of the mark. In the “666” case, just as in the dietary supplements disease claim regulations, the prohibition did not deny the owner *all* economically viable use of the mark or name. Moreover, these kinds of restrictions “will not allow one manufacturer to use another’s trademark or trade name,”<sup>252</sup> nor is the government taking the “trademark or trade name for its own use.”<sup>253</sup>

These kinds of restrictions on the use of intellectual property will, as the FDA concluded with respect to the dietary supplement regulations, rarely (if

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245. *See id.*

246. *Id.*

247. *See U.S. v. 70½ Dozen Bottles “666,” supra* note 163, at 89.

248. *Id.*

249. *Id.*

250. *See id.* at 93.

251. *Id.* at 91.

252. *Dietary Supplements Regulations, supra* note 163, at 1042.

253. *Id.*

ever) rise to the level of a constitutional “taking” under the Fifth Amendment.<sup>254</sup> Nonetheless, other FDA regulations, particularly those that *do* allow one manufacturer to use another’s intellectual assets may present legitimate claims of a taking. That is the topic explored in Part IV. Before considering when appropriations of intellectual property, such as in *SmithKline*, may be constitutional takings, it is important to explore in Part III the recent cases that allow states to appropriate and infringe intellectual property rights and restrict Congress’ ability to protect IP rights. Then in Part IV we may consider whether a takings theory of infringement would also apply to the states.

### III. INTELLECTUAL PROPERTY AT THE MERCY OF THE SOVEREIGN STATES

If *SmithKline* represents a judicial willingness to sacrifice intellectual property rights on the altar of administrative deference, then it should be viewed alongside recent cases in which the courts have commanded deference to states’ rights. These cases, *Florida Prepaid*,<sup>255</sup> *Chavez v. Arte Publico Press*,<sup>256</sup> and *College Savings*,<sup>257</sup> curtailed federal intellectual property protection against the states on the ground that the protections were beyond the scope of Congress’ constitutional powers. Similarly, the Sonny Bono Copyright Term Extension Act of 1998,<sup>258</sup> which extended copyright protection for existing and future copyrights by an additional twenty years, survived a recent scare<sup>259</sup> in which one judge on a three-judge panel of the United States Court of Appeals for the D.C. Circuit argued that the extension was beyond the scope of Congress’ power under the Patent and Copyright Clause of the Constitution.<sup>260</sup> The purpose of this Part is not to address the merits of the doctrinal underpinnings of these decisions. For example, the sovereign immunity jurisprudence of the current five-to-four majority on the Supreme Court may well be correct, and if so, then it would be anomalous for it not to apply to federal intellectual property protections as much as any

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254. *See id.* at 1041-43.

255. Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627 (1999).

256. 204 F.3d 601 (5th Cir. 2000).

257. College Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 527 U.S. 666 (1999).

258. Pub L. No. 105-298, 112 Stat. 2827 (1998); 17 U.S.C. §§ 302, 304 (2000).

259. Eldred v. Reno, 239 F.3d 372 (D.C. Cir. 2001), *reh’g denied*, 255 F.3d 849 (D.C. Cir. 2001), *cert granted* No. 01-618, 70 U.S.L.W. 3292 (Feb. 25, 2002).

260. U.S. CONST. art. I, § 8, cl. 8; *see Eldred*, 239 F.3d at 380 (Sentelle, J., dissenting in part). Judge Sentelle, joined by Judge Tatel, also dissented from the denial of rehearing en banc. *See Eldred v. Ashcroft*, 255 F.3d 849, 852 (D.C. Cir. 2001) (Sentelle, J., dissenting from denial of rehearing en banc). The fate of the Act is still an open question as the Supreme Court granted certiorari. *See Eldred v. Ashcroft*, No. 01-618, 70 U.S.L.W. 3292 (Feb. 25, 2002).



other congressional enactment.<sup>261</sup> Nonetheless, that does not make the real-world reduction of IP protection any less significant. Therefore, this Part will address these recent decisions and the scope of their effect on IP rights as applied against the states. Part IV will explore a takings theory of infringement, which could enhance or ensure intellectual property protection against both the federal and state governments.

#### A. *The Effect of Sovereign Immunity on Intellectual Property*

In some ways, IP rights may be the victims of “friendly fire” in the current doctrinal conflict over the proper scope of state sovereign immunity raging in the United States Supreme Court.<sup>262</sup> The majority, which struck down the Patent and Plant Variety Protection Remedy Clarification Act<sup>263</sup> (amending the patent laws to expressly abrogate the states’ sovereign immunity), consists of the same justices who have led the charge to restore (or enhance, depending on your point of view) private property rights under the federal Constitution.<sup>264</sup> The Act provided that:

Any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune, under the eleventh amendment of the Constitution of the United States or under any other doctrine of sovereign immunity, from suit in Federal court by any person . . . for infringement of a patent under section 271, or for any other violation under this title.<sup>265</sup>

Congress justified the Act under three sources of constitutional authority: The Patent and Copyright Clause,<sup>266</sup> the Commerce Clause,<sup>267</sup> and Section

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261. One commentator suggests that applying sovereign immunity in intellectual property cases may not produce “odd” or “unjust” results at all. See Eugene Volokh, *Sovereign Immunity and Intellectual Property*, 73 SO. CAL. L. REV. 1161, 1166 (2000).

262. Every sovereign immunity decision, *Seminole Tribe of Florida v. Florida*, 517 U.S. 44 (1996), *Florida Prepaid Postsecondary Education Expense Bd. v. College Savings Bank*, 527 U.S. 627 (1999), *Alden v. Maine*, 527 U.S. 706 (1999), and *Kimel v. Florida Bd. of Regents*, 528 U.S. 62 (2000), has been decided by a five-to-four vote, with Chief Justice Rehnquist and Justices O’Connor, Scalia, Kennedy, and Thomas, comprising the majority and Justices Stevens, Souter, Ginsburg, and Breyer in dissent.

263. 35 U.S.C. §§ 271(h), 296(a) (2000).

264. See, e.g., *Nollan v. California Coastal Comm’n*, 483 U.S. 825 (1987); *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003 (1992); *Dolan v. City of Tigard*, 512 U.S. 374 (1994). With the exception of *Nollan*, which pre-dates Justice Thomas’s tenure on the court, Chief Justice Rehnquist and Justices O’Connor, Scalia, Kennedy, and Thomas have consistently been in the majority in these and other “property rights” cases. In Part IV.D, I will examine how *Florida Prepaid* brought two of the major jurisprudential “projects” of the Rehnquist Court into conflict: states’ rights and property rights.

265. 35 U.S.C. § 296(a) (2000).

266. U.S. CONST. art. I, § 8, cl. 8.

267. *Id.* at cl. 3.

Five of the Fourteenth Amendment.<sup>268</sup> However, the *Florida Prepaid* Court held that, as *Seminole Tribe*<sup>269</sup> “makes clear,” Congress “may not abrogate state sovereign immunity pursuant to its Article I powers.”<sup>270</sup> Therefore the Patent Remedy Act could not be sustained either under the Commerce Clause or the Patent and Copyright Clause. The only remaining ground for sustaining the act was Congress’ remedial powers under Section Five of the Fourteenth Amendment, which have been held to explicitly abrogate state sovereign immunity.<sup>271</sup>

Before examining the justifications offered and rejected for abrogation pursuant to the Fourteenth Amendment, it is worth pausing to allow the Court’s pronouncement on the Patent and Copyright Clause to sink in. Under the Court’s reasoning, Congress has *no affirmative power* to protect patents and copyrights from state infringement, only a *remedial power*, which did not even exist until the passage of the Civil War Amendments. This is despite the fact that the “Constitution vests Congress with plenary authority over patents and copyrights” and that “[n]early 200 years ago, Congress provided for exclusive jurisdiction of patent infringement litigation in the federal courts.”<sup>272</sup> This heretofore unrecognized (or unlitigated) limitation on patent rights is breathtaking to consider. James Madison defended the Patent and Copyright Clause stating: “The utility of this power will scarcely be questioned . . . The States cannot separately make effectual provision for either [patents or copyrights], and most of them have anticipated the decision of this point, by laws passed at the instance of Congress.”<sup>273</sup> Similarly, no less of a constitutional authority than Justice Story said of the Patent and Copyright clause: “It is beneficial to all parties, that the national government should possess this power . . . because, otherwise, [authors and inventors] would be subjected to the varying laws and systems of the different states on this subject, which would impair, and might even destroy the value of their rights.”<sup>274</sup> Thus, there is historic recognition of the need for a national, uniform patent and copyright system.

Given this history, it is somewhat remarkable to discover, at the turn of the Millennium, that the states themselves were originally exempted from this system. Whether a principled distinction could be drawn between

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268. *Id.* at amend. XIV, § 5.

269. *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44 (1996).

270. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 636 (1999).

271. *Fitzpatrick v. Bitzer*, 427 U.S. 445, 456 (1976).

272. *Fla. Prepaid*, 527 U.S. at 648 (Stevens, J., dissenting).

273. THE FEDERALIST NO. 43, at 267 (James Madison) (H. Lodge ed., 1908).

274. JOSEPH STORY, COMMENTARIES ON THE CONSTITUTION OF THE UNITED STATES 402, § 502 (Rotunda & Nowak eds., 1987).

Congress' power to abrogate sovereign immunity under the Patent and Copyright Clause, but not the Commerce Clause, is a question for others to ponder. Nonetheless, where states have no power to act,<sup>275</sup> and whenever state autonomy or "state sovereignty does not limit national authority to impose certain obligations on the states—for example, to prohibit them from infringing people's patents or copyrights . . .—then what independent value of federalism is served by inserting sovereign immunity as an additional barrier to effective enforcement of these obligations?"<sup>276</sup>

Turning to Congress' power under the Fourteenth Amendment, "appropriate" legislation pursuant to the Enforcement Clause of the Fourteenth Amendment can abrogate state sovereignty. The question is what constitutes "appropriate" legislation. The Court addressed the scope of Section Five in *City of Boerne v. Flores*.<sup>277</sup> "There must be a congruence and proportionality between the injury to be prevented or remedied and the means adopted to that end."<sup>278</sup> To exercise the remedial powers of Section Five, Congress must "identify conduct transgressing the Fourteenth Amendment's substantive provisions, and must tailor its legislative scheme to remedying or preventing such conduct."<sup>279</sup> In the case of the Patent Remedy Act, the underlying conduct at issue is state infringement of patents and the use of sovereign immunity to deny patent owners compensation.<sup>280</sup> The Court concluded, "Congress identified no pattern of patent infringement by the States, let alone a pattern of constitutional violations."<sup>281</sup> Rather, the legislative history indicated that "states are willing and able to respect patent rights" and that Congress did "not have any evidence of massive or widespread violation of patent laws by the States either with or without this State immunity."<sup>282</sup> Based on this lack of evidence, and determining that

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275. Arguably, under the Constitution *itself*, states have no power to issue patents, copyrights and the like, as the Patent and Copyright Clause gives Congress the power to secure "for limited Times to Authors and Inventors the *exclusive* Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8 (emphasis added). For this to be an exclusive right, it has to be solely Congress' to grant. By contrast, the Interstate Commerce Clause does not have any explicit mention of exclusivity. See U.S. CONST. art. I, § 8, cl. 3. The "exclusivity" has arisen from the so-called "dormant Commerce Clause" jurisprudence of the Supreme Court. See, e.g., *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *Cooley v. Bd. of Wardens*, 53 U.S. (12 How.) 299 (1851); *City of Philadelphia v. New Jersey*, 437 U.S. 617 (1978). Thus, perhaps the text of the two sources of congressional power suggests the basis for a principled distinction – but that is a matter for others to consider.

276. David L. Shapiro, *The 1999 Trilogy: What is Good Federalism?*, 31 RUTGERS L.J. 753, 754-55 (2000). Professor Shapiro responds to his rhetorical question: "The answer, I believe, is none, and indeed a contrary answer strikes me as incompatible with the basic notion not only of a government of law but of a government under law." *Id.* at 755.

277. 521 U.S. 507 (1997).

278. *Id.* at 520.

279. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 639 (1999).

280. See *id.*

281. *Id.*

282. *Id.*

Congress only viewed state remedies to infringement “less convenient than federal remedies” rather than “constitutionally inadequate,”<sup>283</sup> the Court found that the Patent Remedy Act did not “respond to a history of ‘widespread and persisting deprivation of constitutional rights’ of the sort congress has faced in enacting proper prophylactic § 5 legislation.”<sup>284</sup> As the provisions could not be understood as remedial, they could not be sustained.<sup>285</sup> Further, even if they were remedial, the scope of the Act was too broad – as the scope of infringement reaches negligent and induced infringement, regardless of intent.<sup>286</sup> Such actions do not “deprive” a person of “property within the meaning of the Due Process Clause.”<sup>287</sup> Thus, the upshot of *Florida Prepaid* is that some states will be able to infringe patent rights with impunity until it rises to a level deserving of “remedial” action by Congress. Even then, patent holders may have to settle for a state forum, despite the interests in uniformity that led to the creation of the United States Court of Appeals for the Federal Circuit.<sup>288</sup> Finally, states can never be forced to comply with the entirety of the patent laws as not all statutory acts of infringement would rise to the level of constitutional violations if committed by a state. Make no mistake, *Florida Prepaid* cuts deep into the heart of patent protection against state infringers.

The *Florida Prepaid* decision on the Patent Remedy Act has already spawned progeny. *Chavez v. Arte Publico Press*,<sup>289</sup> which involved Congress’ attempt to abrogate state sovereign immunity for copyright infringement and violations of the Lanham Act,<sup>290</sup> was considered no fewer than three times by a panel of the Fifth Circuit due to remands from the United States Supreme Court following *Seminole Tribe*, and from the en banc Fifth Circuit following *Florida Prepaid*.<sup>291</sup> Ultimately, the IP owner lost.

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283. *Id.* at 644.

284. *Id.* at 645.

285. *See id.* at 646-48.

286. *See id.* at 644-45.

287. *Id.*

288. *See id.* at 652-53 (Stevens, J., dissenting).

289. 204 F.3d 601 (5th Cir. 2000) [hereinafter *Chavez III*].

290. Copyright Remedy Clarification Act, 17 U.S.C. §§ 501, 511 (2000); Trademark Remedy Clarification Act, 15 U.S.C. §§ 1122, 1125(a) (2000).

291. Another panel of the Fifth Circuit summarily applied the Supreme Court’s decision in *Florida Prepaid* to the Copyright Remedy Clarification Act and affirmed the judgment of the district court that the lawsuit against the state could not be sustained in light of *Florida Prepaid*. *See Rodriguez v. Texas Comm’n on the Arts*, 199 F.3d 279 (5th Cir. 2000) (noting that the language and reasoning in the Copyright Remedy Clarification Act was nearly identical to that in the Patent Remedy Act).

The plaintiff in *Chavez* sued the University of Houston for infringing her copyright by continuing to publish her book without her consent. Although this was clearly a violation of a property interest,<sup>292</sup> the court held a cause of action in federal court could not be justified pursuant to Section Five of the Fourteenth Amendment. Despite the fact that the legislative history for the Copyright Remedy Clarification Act documented “a few more instances of copyright infringement than the [Patent Remedy Act] legislative history did of patent violations” the Fifth Circuit found that the Copyright Remedy “exhibit[ed] similar deficiencies.”<sup>293</sup> There was no “evidence of a pattern of unremedied copyright infringement by the States;” rather, “Congress worried principally about the potential for future abuse.”<sup>294</sup> Like the *Florida Prepaid* Court, the *Chavez* court also noted that Congress “barely considered the availability of state remedies for infringement.”<sup>295</sup> Further, the *Chavez* court observed, “Congress rejected the idea of granting state courts concurrent jurisdiction over copyright cases.”<sup>296</sup> As in *Florida Prepaid*, the Court found the scope of copyright infringement to be broader than what would be constitutional violations, because “[c]opyright infringement actions, like those for patent infringement, ordinarily require no showing of *intent* to infringe.”<sup>297</sup> Thus, we see the scope of *Florida Prepaid* covers both patents and copyrights, leaving holders of these property rights, conferred pursuant to the United States Constitution, with no remedy save that which a state might choose to give it—assuming that such a remedy is not preempted by the exclusive federal jurisdiction provisions of patent and copyright laws—and certainly no guarantee of the rights expressly conferred by Congress. The irony is that in rejecting arguments that Congress was responding to concerns over the potential for future abuse by the states, these decisions may usher in such abuse at a time when such property rights are becoming increasingly central to innovation and the economy.<sup>298</sup> Given these courts’ rejection of the findings of fact by Congress in both the Patent and Copyright Remedy Clarification Acts, and similar rejections of fact-finding in cases such as *United States v. Morrison*,<sup>299</sup> it is

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292. See *Chavez v. Arte Publico Press*, 157 F.3d 282, 288 (1998) [hereinafter *Chavez II*].

293. *Chavez III*, 204 F.3d at 605.

294. *Id.* at 606.

295. *Id.*

296. *Id.* at 607.

297. *Id.* (emphasis added).

298. See, e.g., sources cited *supra* note 7.

299. 529 U.S. 598 (2000) (holding the Violence Against Women Act to be beyond the scope of Congress’ Commerce Clause power and beyond the scope of its Enforcement Clause remedial powers under the Fourteenth Amendment, notwithstanding extensive findings of fact documenting constitutional violations in at least twenty-one states and pervasive gender-based stereotypes hampering state legal systems, sometimes constitutionally so).

hard to imagine the scope and the extent of infringement of intellectual property rights by the states that must occur before Congress can permissibly respond.

*B. Limits on Congress' Power to Protect Other IP From State Infringement*

*Florida Prepaid* and *Chavez* represent failed attempts to regulate state infringement of well-established intellectual property rights: patent and copyright. There Congress had exceeded its power under Section Five of the Fourteenth Amendment because the remedy was not congruent and proportional to the alleged harm. However, following from *City of Boerne*,<sup>300</sup> there must not only be congruence, but Congress can only be protecting a constitutional right *as defined by the Supreme Court*. Congress' remedial power is designed to enforce the provisions of the Fourteenth Amendment, not to "decree the substance of the Fourteenth Amendment's restrictions on the States."<sup>301</sup> Thus, in *Boerne*, the Religious Freedom and Restoration Act was unconstitutional as applied to the states, because it imposed obligations on the states that the Free Exercise Clause (incorporated through the Fourteenth Amendment) did not require.<sup>302</sup> Similarly, in creating an intellectual property rights enforceable against the states pursuant to the Fourteenth Amendment, Congress is limited to creating a "property right" that is protected by the Due Process Clause.

The Trademark Remedy Clarification Act ("TRCA") subjected states to suits brought under the Lanham Act for false and misleading advertising and misrepresentation, as well as misappropriation.<sup>303</sup> Thus, in *College Savings* the question was whether that provision was a constitutionally permissible abrogation of state sovereign immunity or did it reach beyond the constitutional definition of "property."<sup>304</sup> The plaintiff in *College Savings* argued that Congress enacted the TRCA to protect two (intellectual) property rights: "(1) a right to be free from a business competitor's false advertising about its own product, and (2) a more generalized right to be secure in one's business interests."<sup>305</sup> However, the Court, per Justice Scalia, rejected them, concluding, "Neither of these qualifies as a property right

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300. 521 U.S. 507 (1997).

301. *Id.* at 508.

302. *Id.*

303. 15 U.S.C. § 1125(a) (2000).

304. *See* Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd. 527 U.S. 666, 667 (1999).

305. *Id.* at 672.

protected by the Due Process Clause.”<sup>306</sup> Rather, the Court described what would qualify as a property right:

The hallmark of a protected property interest is the right to exclude others. That is “one of the most essential sticks in the bundle of rights that are commonly characterized as property.” *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979). That is why the right that we all possess to use the public lands is not the “property” right of anyone—hence the sardonic maxim, explaining what economists call the “tragedy of the commons,” *res publica, res nullius*. The Lanham Act may well contain provisions that protect constitutionally cognizable property interests—notably, its provisions dealing with infringement of trademarks, which are the “property” of the owner because he can exclude others from using them. See, e.g., *K mart Corp. v. Cartier, Inc.*, 485 U.S. 176, 185-186 (1988) (“Trademark law, like contract law, confers private rights, which are themselves rights of exclusion. It grants the trademark owner a bundle of such rights”). The Lanham Act’s false-advertising provisions, however, bear no relationship to any right to exclude; and Florida Prepaid’s alleged misrepresentations concerning its own products intruded upon no interest over which petitioner had exclusive dominion.<sup>307</sup>

As there was “no deprivation of [constitutionally protected] property at issue,”<sup>308</sup> the Court found that Congress could not abrogate state sovereign immunity pursuant to Section Five of the Fourteenth Amendment and did not reach the proportionality analysis discussed in Part III.A., above.

*College Savings* thus provides a *substantive* limitation on Congress’ power to define property rights, and particularly more ephemeral intellectual property rights, that may be enforced against the states in federal courts.<sup>309</sup> This limitation, focused on the “right to exclude,” curtails Congress’ ability to create intellectual property rights. As the intellectual assets become less like “real property,” it becomes harder for Congress to provide protection against the states. The dissent suggested that *Seminole Tribe* and its progeny, such as *College Savings*, “threaten[] the Nation’s ability to enact economic legislation needed for the future. . . .”<sup>310</sup> Justice Stevens, in dissent, argued that

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306. *Id.* at 673.

307. *Id.* (footnote omitted).

308. *Id.*

309. Congress also may not mandate that state courts open their doors to such claims. *Alden v. Maine*, 527 U.S. 706 (1999).

310. *College Savings*, 527 U.S. at 701 (Breyer, J., dissenting).

The activity of doing business, or the activity of making a profit, is a form of property. The asset that often appears on a company's balance sheet as "good will" is the substantial equivalent of that "activity." It is the same kind of "property" that Congress described in § 7 of the Sherman Act, 26 Stat. 210 and in § 4 of the Clayton Act, 38 Stat. 731. A State's deliberate destruction of a going business is surely a deprivation of property within the meaning of the Due Process Clause.<sup>311</sup>

Justice Stevens conceptualizes "property" broadly, but even a narrower definition linked to the "right to exclude" could reach "good will" – in fact, that is the very value of a trademark. Nearly any right can be recast as a right to exclude. For example, a prohibition on false advertising can be thought of as the right to exclude anyone from speaking falsely about your product. The majority's approach, however, seems to go further than requiring a right to exclude, but almost a quasi-tangible embodiment. Thus, when Justice Scalia suggests that we could not have a property right in public lands, it may be that this is driven not only by the lack of exclusion, but also the inability to point to a *particular* piece and say "it is mine." The majority approach, while setting boundaries on Congress, seems tied to traditional conceptualizations, which may not fit intellectual property as technology continues to develop. Justice Breyer feared that the Court's decision

[w]ill make it more difficult for Congress to create, for example, a decentralized system of individual private remedies, say a private remedial system needed to protect intellectual property, including computer-related educational materials, irrespective of the need for, or importance of, such a system in a 21<sup>st</sup> century advanced economy.<sup>312</sup>

Under the majority's approach, various IP rights seem suspect (as potentially applied to the states). For example, the exclusive right "to prepare derivative works based on the copyrighted work"<sup>313</sup> is particularly hard to conceptualize. The scope of what is a "derivative work" is potentially boundless. Unlike a patent right or the right to reproduce a copyrighted work, the metes and bounds of the property interest are ill-defined. A limited, traditional view of property would be hard-pressed to

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311. *Id.* at 693 (Stevens, J., dissenting).

312. *Id.* at 701-02 (Breyer, J., dissenting).

313. 17 U.S.C. § 106(2) (2000).



embrace this right. Similarly, IP rights set forth in the Visual Artists Rights Act of 1990,<sup>314</sup> which include the artist's right to claim authorship of the work, to prevent the use of her name on works she did not create, and to prevent the use of her name on works that have been modified or distorted, as well as limited rights to object to the modification or destruction of their original works,<sup>315</sup> do not fit traditional American notions of property, or perhaps the traditional notion of the right to exclude. Were it to be applied against the states, the objections to the definition of "property" would be similar to those raised in *College Savings*. Yet, such rights, commonly called "moral rights," which encompass protections of the "personality" of the author/creator, have a rich tradition in continental Europe.<sup>316</sup>

The Court's reluctance to give "property" a broad definition in many ways parallels developments in standing doctrine. In *Lujan v. Defenders of Wildlife*,<sup>317</sup> the Court, again per Justice Scalia, rejected standing to challenge administrative action under the enforcement provisions of the Endangered Species Act<sup>318</sup> in part on the grounds that the plaintiffs could not assert a mere "procedural injury." Rather a direct and personal injury (or imminent injury) must be shown. Of course, the Court would allow a plaintiff to seek to enforce a procedural requirement, "the disregard of which could impair a separate concrete interest of theirs."<sup>319</sup> In *College Savings*, the Court is again looking for a "concrete interest." If the reasoning in *Lujan* is indeed parallel, then there is at least one member of the *College Savings* majority who should be expected to consider non-traditional property interests created by Congress. In *Lujan*, Justice Kennedy concurred and noted, "[W]e must be sensitive to the articulation of new rights of action that do not have clear analogs in our common-law tradition."<sup>320</sup> He further suggested, "Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before."<sup>321</sup> If this is

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314. *Id.* § 106A.

315. ROBERT P. MERGES, ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 483-86 (2d ed. 2000).

316. *Id.* at 483, 543-48.

317. 504 U.S. 555 (1992).

318. 16 U.S.C. § 1536(a)(2) (2000).

319. *Lujan*, 504 U.S. at 572.

320. *Id.* at 580 (Kennedy, J., concurring in part and concurring in judgment). Justice O'Connor, who dissented in *Lujan*, might also be sympathetic to such an argument.

321. *Id.* In the context of standing, one could imagine Congress amending the Endangered Species Act to read: "Every citizen has a right to preservation of all species throughout the world against threats to which actions of the United States government contribute in any way. Any citizen may bring suit in federal court for all appropriate relief for violations of that right." RICHARD H. FALLON, ET AL., *HART AND WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM* 172 (4th ed. 1996). Similarly, Congress could give every citizen "a property right" in federally-owned wetlands, for example. If this right were merely a right to "use" such federal public property, then Justice Scalia's dicta in *College Savings* suggests that it would not meet his constitutional definition of a property right. However, if this right included a right to exclude bulldozers, the case becomes harder. Given Justice Kennedy's commitment to "be sensitive to the articulation of new rights of

true, then Congress should be able to define a property interest, its bounds, and what constitutes violations of it, in such a way that would also be applicable to the states. Perhaps the Lanham Act's false-advertising provisions are too ephemeral to constitute a property right, but it does not follow that other IP rights, though new and abstract, will necessarily be denied protection under the Due Process Clause. Even if they are, Congress can still prohibit infringement by *private* actors. The Lanham Act's false-advertising provisions, for example, are still valid, they simply cannot be used to hold a *state* liable. Limitations on the meaning of "property" under the Fourteenth Amendment will never be *fatal* to intellectual property rights, only to some enforcement against the states.

### C. Substantive Limits on Congress' Power to Protect Intellectual Property

#### 1. Originality as a Constitutional Requirement for Copyright

Although the Fourteenth Amendment only limits Congress' power to create and protect intellectual property rights as against the states, there are other Constitutional limitations to Congress' power to create IP rights altogether. The recent federalism-driven decisions of the Court to discern limitations to Congress' commerce power suggest there are also limitations to Congress' power to grant IP rights under the Patent and Copyright Clause. These limitations, motivated by a desire to keep Congress from encroaching upon the "reserved powers" of the sovereign states, suggested in the Tenth Amendment, do not just apply to IP rights against the states, but to IP rights as against private entities as well.

In the setting of copyright, a unanimous United States Supreme Court announced a significant substantive *constitutional* limitation in *Feist Publications, Inc. v. Rural Telephone Service, Co.*<sup>322</sup> The case explored the extent of copyright protection available to telephone directory white pages: at issue was whether the compilation of names, addresses, and phone numbers was sufficiently "original" to qualify for copyright protection. It is

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action," *Lujan*, 504 U.S. at 579 (Kennedy, J., concurring in part and concurring in judgment), one can imagine a recognition of such a property right. Cf. *FEC v. Akins*, 524 U.S. 11 (1998) (recognizing the power of Congress to confer standing on any citizen suffering the 'injury' of 'inability to receive information' that results from another party's noncompliance with statutory disclosure requirements). In *Akins*, the Court appeared to acknowledge that the interest in access to widely-shared information would not have been actionable at common law. However, congressional action was sufficient to confer standing. Justice Kennedy (along with Chief Justice Rehnquist and Justices Stevens, Souter, and Ginsburg) joined the opinion of Justice Breyer for the majority.

322. 499 U.S. 340 (1991).

well established that “[n]o one may claim originality as to facts.”<sup>323</sup> “This is because facts do not owe their origin to an act of authorship. The distinction is one between creation and discovery: the first person to find and report a particular fact has not created the fact; he or she has merely discovered its existence. . . . Factual compilations on the other hand, may possess the requisite originality.”<sup>324</sup> In *Feist*, the Court made it clear that:

[O]riginality is a constitutional requirement. The source of Congress’ power to enact copyright laws is Article I, § 8, cl. 8, of the Constitution, which authorizes Congress to “secur[e] for limited Times to Authors . . . the exclusive Right to their respective Writings.” In two decisions from the late 19<sup>th</sup> Century . . . this Court defined the crucial terms “authors” and “writings.” In so doing, the Court made it unmistakably clear that these terms presuppose a degree of originality.<sup>325</sup>

Thus, originality circumscribes Congress’s power to create intellectual property rights under the Patent and Copyright Clause. In *Feist*, this meant that raw data entries in the white pages were not copyrightable, despite the “sweat of the brow” involved in assembling such data.<sup>326</sup> As the Court observed:

It may seem unfair that much of the fruit of the compiler’s labor may be used by others without compensation. . . . [H]owever, this is not “some unforeseen byproduct of a statutory scheme.” It is, rather, “the essence of copyright,” and a constitutional requirement. The primary objective of copyright is not to reward the labor of authors, but “[t]o promote the Progress of Science and useful Arts.” Art. I, § 8, cl. 8. To this end, copyright assures authors the right to their original expression, but encourages others to build freely upon the ideas and information conveyed by a work. This principle, known as the idea/expression or fact/expression dichotomy, applies to all works of authorship. As applied to a factual compilation, assuming the absence of original written expression, only the compiler’s selection and arrangement may be protected; the raw

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323. M. NIMMER & D. NIMMER, NIMMER ON COPYRIGHT § 2.11[A], at 2-157 (1990).

324. *Feist*, 499 U.S. at 347-48.

325. *Id.* at 346 (citations omitted).

326. One possibility to protect “sweat of the brow” works such as databases would be legislation pursuant to the *Commerce Clause*, rather than the Patent and Copyright Clause. Thus, H.R. 354 (2000) would have created “a new intellectual property right in the database itself,” which would create a cause of action for “use or extraction of *individual facts* from that database,” while H.R. 1858 (2000) “would provide a form of unfair competition protection against those who take most or all of a database from a database provider in order to enter into competition with that provider.” MERGES, ET. AL., *supra* note 315, at 362-63 (emphasis added). The European Union directive on database protection already has strong “sweat of the brow” protections. *See id.* at 362.

facts may be copied at will. This result is neither unfair nor unfortunate. It is the means by which copyright advances the progress of science and art.<sup>327</sup>

Of course, *Feist* is not limited to phone books. It applies to all factual compilations, including databases,<sup>328</sup> and potentially labels, such as the one at issue in *SmithKline*.

If there is no copyright protection for the white pages, how can there be any protection for product labels? Obviously, if everything on the label is just a “fact” about the product, that information cannot be copyrighted. Nutrition labeling and claims about foods and drugs would all be facts (and in the case of drugs, they would have to be approved to be on the label in the first instance). Such facts could not be the subject of a copyright. However, the arrangement of words, pictures, and so forth on the label, is a protected compilation that has some minimal degree of creativity.<sup>329</sup> Nonetheless, there are only so many ways to put, for example, nutrition information on a label. If everyone uses the same form (much as all white pages alphabetize), then, under the so-called “merger doctrine,” a label may still lack the originality necessary to be copyrightable.<sup>330</sup> In most cases, a label possesses at least some creative component, allowing it (but not the included facts) to fall within the constitutional bounds of copyright. Further, the case for protection arises in part from the FDCA’s broad definition of label, which covers all printed or graphic material accompanying a product.<sup>331</sup> Thus, as in

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327. *Feist*, 499 U.S. at 349-50.

328. See, e.g., John F. Hayden, *Copyright Protection of Computer Databases After Feist*, 5 HARV. J. L. & TECH. 215 (1991); Philip H. Miller, *Life After Feist: Facts, the First Amendment, and the Copyright Status of Automated Databases*, 60 FORDHAM L. REV. 507 (1991); Jane C. Ginsburg, *Creation and Commercial Value: Copyright Protection of Works of Information*, 90 COLUM. L. REV. 1865 (1990). See also MERGES, ET AL., *supra* note 315, at 361-63 (citing these articles and discussing potential protections for “sweat of the brow” investments).

329. *Feist*, 499 U.S. at 346. Cf. *Roth Greeting Cards v. United Card Co.*, 429 F.2d 1106 (9th Cir. 1970) (holding an arrangement of text, art work, and association between art work and text in a greeting card was both original and copyrightable, although the individual elements were not). See also *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 n.5 (2000) (“Here, although the labeling at issue is more creative than that in the ‘familiar’ commercial labeling cases . . . SmithKline’s copyright claim is arguably weaker than even the typical commercial labeling case, because the copyrighted text was submitted to obtain FDA approval and consequent market exclusivity.”).

330. “When there is only one or but a few ways of expressing an idea, then courts will find that the idea behind the work merges with its expression and the work is not copyrightable.” MERGES, ET AL., *supra* note 315, at 384. See also *Morrissey v. Procter & Gamble* 379 F.2d 675 (1st Cir. 1967) (applying the merger doctrine); cf. *Baker v. Selden* 101 U.S. 99 (1879) (developing the division between protectable expression and unprotectable ideas).

331. See 21 U.S.C. § 321(k) & (m) (2000) (“The term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2)

*SmithKline*, “labeling” is not just the factual information on the outside of the Nicorette box, but also includes the accompanying user guide and audio tapes.<sup>332</sup> However, the recognition that “labels themselves have only a limited creative component”<sup>333</sup> suggests that even protected labels are not at the heart of copyright protection, and thus receive less judicial protection from infringement than “familiar copyrighted materials such as sound recordings or books.”<sup>334</sup> Thus, while not explicitly saying so, part of what drove Chief Judge Winter’s decision in *SmithKline* may have been an unexpressed view that labeling, despite any creativity, is simply not worthy of the full protection afforded more “familiar” copyrighted works.

## 2. Constitutional Limits on the Duration and Purpose of IP Rights

The United States Court of Appeals for the D.C. Circuit recently considered the constitutionality of the Sonny Bono Copyright Term Extension Act of 1998<sup>335</sup> in *Eldred v. Reno*.<sup>336</sup> The D.C. Circuit addressed “whether the First Amendment or the Copyright Clause of the Constitution of the United States constrains the Congress from extending for a period of years the duration of copyrights, both those already extant and those yet to come,” and held that neither does.<sup>337</sup> While quickly dispensing with the First Amendment argument on the ground that there is no First Amendment right to make commercial use of the copyrights of others,<sup>338</sup> the court also had to

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accompanying such article.”); *Kordel v. United States*, 335 U.S. 345 (1948) (applying § 321(m) to literature having a common origin as the drugs and used in the sale of the drugs). See generally HUTT & MERRILL, *supra* note 129, at 43-51 (“Scope of ‘Labeling’”).

332. See *SmithKline*, 211 F.3d at 26 (noting that the FDA’s broad interpretation of 21 U.S.C. § 321(k) & (m) encompasses the Nicorette user guide and audiotape). Accord 21 C.F.R. § 202.1(1)(2) (2001) (including “[b]rochures, booklets, . . . sound recordings, . . . and similar pieces of printed, audio, or visual matter descriptive of a drug” as “labeling”).

333. *Quality King Distrib., Inc. v. L’anza Research Int’l, Inc.*, 523 U.S. 135 (1988).

334. *Id.* Cf. *Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 563 (1985) (applying the “fair use” defense, 17 U.S.C. § 107, and noting that the second fair use factor, “the nature of the copyrighted work” reflects the “law[’s] general[] recogni[tion of] a greater need to disseminate factual works than works of fiction or fantasy,” thus providing greater protection for fiction than fact-based work). Cf. *SmithKline*, 211 F.3d at 29 n.5.

Although commercial labeling is clearly copyrightable . . . it has been recognized that the ‘danger lurking in copyright protection for labels is that the tail threatens to wag the dog—proprietors at times seize on copyright protection for the label in order to leverage their thin copyright protection over the text . . . on the label into a monopoly on the typically uncopyrightable product to which it is attached.

*Id.* (quoting I NIMMER ON COPYRIGHT § 2.08[G][2], at 2-138) (citations omitted).

335. Pub. L. No. 105-298, 112 Stat. 2827, 17 U.S.C. §§ 302(a) & (c), 304 (2000).

336. 239 F.3d 372, *reh’g denied*, 255 F.3d 849 (D.C. Cir. 2001), *cert granted* No. 01-618, 70 U.S.L.W. 3292 (Feb. 25, 2002).

337. *Id.* at 373.

338. See *id.* at 375-76. The court noted that “[a]lthough there is some tension between the Constitution’s copyright clause and the first amendment, the familiar idea/expression dichotomy of copyright law, under which ideas are free but their particular expression can be copyrighted, has always been held to give adequate protection to free expression.” *Id.* at 376 (quoting *United Video*,

address the argument that the “limited Times”<sup>339</sup> provision of the Patent and Copyright Clause had been exceeded.

The plaintiff argued that the preamble of the Copyright Clause (“The Congress shall have power . . . To promote the Progress of Science and useful Arts. . . .”<sup>340</sup>) provides a limiting principle to give meaning to “limited Times.” The idea is that the phrase “limited Times” should be read as “reaching only as far as is justified by the preambular statement of purpose: If 50 years are enough to ‘promote . . . Progress,’ then a grant of 70 years is unconstitutional.”<sup>341</sup> The D.C. Circuit rejected this argument and sustained the twenty-year extension, in part based on its previous decision in *Schnapper v. Foley*,<sup>342</sup> where it “rejected the argument ‘that the introductory language of the Copyright Clause constitutes a limit on congressional power.’”<sup>343</sup> Further, the court suggested it would be a valid exercise of Congress’ power under the Patent and Copyright Clause and the Necessary and Proper Clause to grant a term extension as “Congress found that extending the duration of copyrights on existing works would, among other things, give copyright holders an incentive to preserve older works, particularly motion pictures in need of restoration” and thus the “application of the CTEA to subsisting copyrights is ‘plainly adapted’ and ‘appropriate’ to ‘promot[ing] progress.’”<sup>344</sup> Thus, Congress’ power to confer additional protection on copyrights, by extending their period of protected exclusivity, was upheld.

There was a dissenting opinion in *Eldred* from Judge David Sentelle.<sup>345</sup> Had this view prevailed (as it may yet, since the Supreme Court has granted certiorari), there would be a substantive, constitutional limitation on Congress’ ability to extend the protection of patents and copyrights. Judge Sentelle “concur[red] with much of the majority’s opinion,” but dissented “insofar as it holds constitutional the twenty-year or more extension of copyright protection for *existing* works.”<sup>346</sup> The dissent observed that the

Inc. v. FCC, 890 F.2d 1173, 1191 (D.C. Cir. 1989)).

339. U.S. CONST. art. I, § 8, cl. 8.

340. *Id.*

341. *Eldred*, 239 F.3d at 377-78.

342. 667 F.2d 102, 112 (D.C. Cir. 1981).

343. *Eldred*, 239 F.3d at 378 (quoting *Schnapper*, 667 F.2d at 112).

344. *Id.* at 379.

345. *Id.* at 380 (Sentelle, J., dissenting). Judge Sentelle, joined by Judge Tatel, also dissented from the denial of rehearing en banc. *Eldred v. Ashcroft*, 255 F.3d 849, 852 (D.C. Cir. 2001) (Sentelle, J., dissenting from denial of rehearing en banc), *cert granted* No. 01-618, 70 U.S.L.W. 3292 (Feb. 25, 2002). The author was not clerking for Judge Sentelle at the time of the *Eldred* case or the denial of rehearing. As throughout this Article, the views expressed herein are solely those of the author.

346. *Id.* (Sentelle, J., dissenting) (emphasis added).

court must “consider the scope of one of the clauses granting enumerated powers to Congress, specifically, Art. I, § 8, cl. 8” and in “ascertaining the breadth of an enumerated power,” and urged following “the lead of the United States Supreme Court in *United States v. Lopez*,” including “start[ing] with first principles.”<sup>347</sup> This approach requires recognition that our federal government is one of enumerated and therefore *limited* powers, and thus there must be outer limits to these enumerated powers.<sup>348</sup> The dissent “fear[ed] that the rationale offered by the government for the copyright extension, as accepted by the district court and the majority, leads to such an unlimited view of the copyright power as the Supreme Court rejected with reference to the Commerce Clause in *Lopez*.”<sup>349</sup>

Judge Sentelle suggested that the court should look to the language of the Patent and Copyright Clause itself to discern a limiting principle, just as the Supreme Court has done in its recent Commerce Clause jurisprudence.

That clause empowers the Congress to do one thing, and one thing only. That one thing is “to promote the progress of science and useful arts.” How may Congress do that? “By securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” The clause is not an open grant of power to secure exclusive rights. It is a grant of a power to promote progress. The means by which that power is to be exercised is certainly the granting of exclusive rights—not an elastic and open-ended use of that means, but only a securing for limited times.<sup>350</sup>

Clearly, Congress can not secure patent and copyright protection for indefinite or infinite periods, “[h]owever, there is no apparent substantive distinction between permanent protection and permanently available authority to extend originally limited protection.”<sup>351</sup> To limit this power to extend originally limited protection, the dissent suggests that it cannot be

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347. *Id.* at 380-81 (internal citation omitted).

348. *See id.* at 381 (“It would seem to me apparent that this concept of ‘outer limits’ to enumerated powers applies not only to the Commerce Clause but to all the enumerated powers, including the Copyright Clause, which we consider today.”).

349. *Id.*

350. *Id.*

351. *Id.* at 382.

The Congress that can extend the protection of an existing work from 100 years to 120 years; can extend that protection from 120 years to 140; and from 140 to 200; and from 200 to 300; and in effect can accomplish precisely what the majority admits it cannot do directly. This, in my view, exceeds the proper understanding of enumerated powers reflected in the *Lopez* principle of requiring some definable stopping point.

*Id.* In the dissent from rehearing en banc, Judge Sentelle reiterated that “the Court’s construction of the Copyright Clause of the Constitution renders Congress’ power under Art. I, § 8, cl. 8, limitless despite express limitations in the terms of that clause.” *Eldred v. Ashcroft*, 255 F.3d 849, 854 (D.C. Cir. 2001) (Sentelle, J., dissenting from denial of rehearing en banc), *cert granted* No. 01-618, 70 U.S.L.W. 3292 (Feb. 25, 2002).

applied retroactively to preexisting copyrighted works, because such retroactive extension does not promote the useful arts.<sup>352</sup> Thus, under the dissenter's view, "the extension of exclusivity previously secured" is not within the scope of the Patent and Copyright Clause and is not constitutional.<sup>353</sup>

If adopted (as it may yet be by the Supreme Court), Judge Sentelle's view would obviously not affect all IP rights, but it would tie Congress' hands in further protecting already existing intellectual property pursuant to the Patent and Copyright Clause. The three previous extensions of copyright protection that have occurred would be unconstitutional.<sup>354</sup> Further, the patent term extension for pre-existing patents on products that are subject to regulation under the FDCA,<sup>355</sup> could be unconstitutional. That provision is designed to "restore" part of the period lost due to regulatory review by the FDA.<sup>356</sup> Perhaps the restorative nature of the extension, and its relationship to the purpose of promoting the progress of science would be enough of a constraint to limit the scope of this enumerated power. In construing the statutory provisions of the patent extension, the United States Court of Appeals for the Federal Circuit noted that "the term of the patent may be given only one *restoration* extension."<sup>357</sup> Even if the patentee has multiple products under one patent that are delayed different periods of time by FDA approval, the patentee can only receive one restoration period, which only applies "to the product on which the extension was based," not all other products covered by the patent.<sup>358</sup> Nonetheless, Judge Sentelle's approach calls the permissibility of even this limited, restorative extension into question.

Ultimately Judge Sentelle may have the better argument, at least regarding general, non-restorative extension. I suspect he does. After all, what, other than the introductory language to the Patent and Copyright Clause, would prohibit Congress from granting a one thousand year term? This would be a "limited time," but cannot be said to have any rational relation to promoting science and the useful arts. Similarly, what would

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352. See *Eldred*, 239 F.3d at 382. To buttress his position, Judge Sentelle noted that "[t]he government has offered no tenable theory as to how retrospective extension can promote the useful arts." *Id.*

353. *Id.*

354. See Act of Feb. 3, 1831 § 1, 4 Stat. 436-39; Act of March 4, 1909 § 23, 35 Stat. 1075-88; Pub. L. No.94-553 § 301, 90 Stat. 2541-2602 (1976).

355. 35 U.S.C. § 156 (2000). See generally DONALD S. CHISUM, V CHISUM ON PATENTS § 16.04[5] (1997).

356. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546-47 (Fed. Cir. 1996).

357. *Id.* at 1547 (emphasis in original).

358. *Id.* at 1547.



preclude Congress from incrementally increasing the term of, e.g., copyright protection to effectively provide infinite (or at least indefinite) protection? Some suggest that this “copyright creep” has already occurred. Congress extended terms throughout the 1960’s, in 1976, and now again in 1998, just in time to intercept “[p]op icons such as Mickey Mouse, books such as *The Great Gatsby*, films such as *The Jazz Singer*, [and] musicals such as *Show Boat*, [all] poised to enter the public domain” and give their owners extended exclusivity.<sup>359</sup> Nonetheless, it must be acknowledged that Judge Sentelle’s approach would result in further judicial limitations on Congress’ ability to create and protect intellectual property rights. Thus, whether it be in the name of administrative deference, as in *SmithKline*, or sovereign immunity, as in *Florida Prepaid*, or the doctrine of limited and enumerated powers, as Judge Sentelle urged in *Eldred*, these cases demonstrate a judicially-led curtailing (or attempted curtailing) of congressionally enacted intellectual property rights.

#### IV. TOWARDS A “TAKINGS” THEORY OF INFRINGEMENT: PROVIDING “JUST COMPENSATION”

Parts I through III have examined governmental intrusions on and infringement of intellectual property rights, without compensation, that were sanctioned by administrative agencies, Congress, or the courts. Part IV explores the applicability of a constitutional remedy that in many cases may be available to the intellectual property owner, against both federal and state entities. That remedy is the Takings Clause of the Fifth Amendment, applicable to the states through Fourteenth Amendment, which provides: “nor shall private property be taken for public use, without just compensation.”<sup>360</sup> There are three distinct elements to this provision: (1) a taking of private property; (2) for public use;<sup>361</sup> (3) with just compensation. In most Takings Clause cases the issue is whether a taking has occurred in the first instance, and in that context, usually the dispute is over the impact of government regulations on a property owner.

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359. Daren Fonda, *Copyright Crusader*, BOSTON GLOBE MAG., Aug. 29, 1999, available at <http://www.boston.com/globe/magazine/8-29/featurestory1.shtml>.

360. U.S. CONST. amend. V.

361. The “public use” requirement is actually rather thin, a factor that will be important in the intellectual property context. “The ‘public use’ requirement is . . . coterminous with the scope of a sovereign’s police powers.” *Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229, 240 (1984). Thus, “where the exercise of the eminent domain power is rationally related to a conceivable public purpose, the Court has never held a compensated taking to be proscribed by the Public Use Clause.” *Id.* at 241. In *Hawaii Housing*, the Court sustained a legislative scheme where “property taken outright by eminent domain is transferred in the first instance to private beneficiaries” stating that it “long ago rejected any literal requirement that condemned property be put into use for the general public” and that “it is only the taking’s purpose, and not its mechanics, that must pass scrutiny under the Public Use Clause.” *Id.* at 244. The fact that a government’s eminent domain power is used to the benefit of individuals, rather than the public at large, is no barrier, so long as there is an overarching public purpose.

The Rehnquist Court gave the Takings Clause life and breadth, providing property owners remedies against government regulations that “go too far.”<sup>362</sup> Thus, it is a ripe opportunity for IP owners to seek broader application of the Takings Clause to governmental actions that would constitute infringement. A takings theory of infringement would treat government infringement as a taking, requiring “just compensation.” Section A reviews the Supreme Court’s takings jurisprudence, the doctrinal bases for determining that a taking has occurred, and discusses an analytical framework for approaching takings. Section B applies this jurisprudence to intellectual property by first considering what IP constitutes “property” for the purposes of the Takings Clause, and then examining how infringement fits within the takings mold. The Court has given some guidance as to how traditional forms of intellectual property may be taken. Further, Congress has also created special remedies for some federal government infringement that may be based on recognition of the Fifth Amendment’s guarantees of just compensation. These will also be explored in Section B. In Section C, I apply the takings jurisprudence to the *SmithKline* case and consider whether the facts in that case constitute a taking, and if not, what, if any, similar circumstances would give rise to a taking. Finally, Section D considers application of the Takings Clause to the states, and whether it, as applied through the Fourteenth Amendment, provides a path around *Florida Prepaid*, *Alden*, and sovereign immunity generally into state, and perhaps federal, court for state acts of infringement.

### A. Takings Jurisprudence

Before considering how intellectual property rights should be analyzed under the Takings Clause, it is important to examine the conceptual framework under which the Supreme Court has treated takings of “real” property. “The question of what constitutes a ‘taking’ for purposes of the Fifth Amendment has proved to be a problem of considerable difficulty.”<sup>363</sup> It is recognized that “Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law”;<sup>364</sup> however, this is subject to the “oft-cited maxim that, ‘while property may be regulated to a certain extent, if

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362. See, e.g., *Nollan v. Cal. Coastal Comm’n*, 483 U.S. 825 (1987); *Lucas v. S.C. Coastal Council*, 505 U.S. 1003 (1992); *Dolan v. City of Tigard*, 512 U.S. 374 (1994); *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687 (1999).

363. *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 123 (1978).

364. *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 413 (1922).

regulation goes too far it will be recognized as a taking.”<sup>365</sup> Yet, in the years of takings jurisprudence succeeding Justice Holmes’s pronouncement of this “general rule,”<sup>366</sup> the Supreme Court has “generally eschewed any ‘set formula.’”<sup>367</sup> Rather, determinations of takings have been described as “essentially ad hoc, factual inquiries,”<sup>368</sup> depending “upon the particular facts,”<sup>369</sup> and requiring “complex factual assessments of the purposes and economic effects of government actions.”<sup>370</sup> The Court has, nonetheless, identified “two discrete categories of regulatory action as compensable without case-specific inquiry. . . .”<sup>371</sup> These two per se categories of takings are “physical invasion” of property and “regulation den[ying] all economically beneficial or productive use of land.”<sup>372</sup>

Although the picture appears rather muddled,<sup>373</sup> the Court’s approach to takings cases can be grouped into four categories, each approached somewhat differently.<sup>374</sup> These categories are (1) Physical Invasion of Property; (2) Deprivation of a “Core” Property Right; (3) Linkage Conditions – Unconstitutional Conditions; and (4) Regulatory Takings. As we will see in Section B, the first category, “Physical Invasion of Property” is of limited utility in the intellectual property context, unless a strong analog to invasion can be identified. We will also see that the second category, while potentially quite relevant if applied to the “right to exclude,” is effectively limited following cases such as *PruneYard Shopping Center v. Robins*.<sup>375</sup> Nonetheless, this four-pronged analytical framework is useful in distinguishing when government action is per se a taking, and when a

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365. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1014 (1992) (quoting *Pennsylvania Coal*, 260 U.S. at 415).

366. *Pennsylvania Coal*, 260 U.S. at 415.

367. *Lucas*, 505 U.S. at 1015 (quoting *Penn Central*, 438 U.S. at 124).

368. *Penn Central*, 438 U.S. at 124.

369. *Pennsylvania Coal*, 260 U.S. at 413.

370. *Yee v. City of Escondido*, 503 U.S. 519, 523 (1992). See also *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 720 (1999) (collecting cases).

371. *Lucas*, 505 U.S. at 1015.

372. *Id.*

373. Muddled may be an understatement. The Court’s general preference for balancing (weighing factors such as “reasonableness”) but having some “per se” exceptions carved out is reminiscent of its treatment of antitrust claims under section 1 of the Sherman Act, 15 U.S.C. § 1. See, e.g., *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (“[M]ost antitrust claims are analyzed under a ‘rule of reason,’ according to which the finder of fact must . . . tak[e] into account a variety of factors . . . . Some types of restraints, however . . . are deemed unlawful *per se*.”). The Court’s antitrust analysis has never been accused of being at the pinnacle of clarity. Analyzing which restraints fall into the per se category and weighing the factors under the “rule of reason” is a in an indeterminate and confused exercise at best. See generally, Terry Calvani, *The Rule of Reason and the Per Se Rule: Some Thoughts on the Rule of Reason*, SE47 A.L.I.-A.B.A. 25 (2000).

374. Much of this categorization is derived from JOSEPH WILLIAM SINGER, PROPERTY LAW: RULES, POLICIES, AND PRACTICES § 12.2, at 1252-62, 1282-86 (2d ed. 1997). Professor Singer described this four-category analytical approach in his lectures on Property Law at Harvard Law School in December, 1998.

375. 447 U.S. 74 (1980).

balancing test is appropriate – and what factors should be balanced. The framework also provides a starting point for analyzing takings of intellectual property.

### 1. Physical Invasion of Property

“[P]hysical intrusion by government” has “long [been] considered” a “property restriction of an unusually serious character for purposes of the Takings Clause.”<sup>376</sup> Thus, “[w]hen faced with a constitutional challenge to a permanent physical occupation of real property [the] Court has invariably found a taking.”<sup>377</sup> In reaching this conclusion, the reasonableness of the property invasion does not matter, nor does the extent of impact on the property owner. Rather, as the *Loretto* Court observed, where the “‘character of the governmental action’[] is a permanent physical occupation of property, [the Court’s] cases uniformly have found a taking to the extent of the occupation, without regard to whether the action achieves an important public benefit or has only minimal economic impact on the owner.”<sup>378</sup> Thus, *Loretto* and *Lucas* both recognize permanent physical invasions as per se takings. As the *Lucas* Court observed: “In general . . . no matter how minute the intrusion, and no matter how weighty the public purpose behind it, we have required compensation.”<sup>379</sup>

This per se approach is explained by the Court’s conceptualization of property rights, which may be instructive in seeking an IP analog to physical invasion. Property rights in a physical thing have been described as the rights to “possess, use and dispose of it.”<sup>380</sup> Thus, by permanently physically occupying property, the government “effectively destroys *each* of these rights.”<sup>381</sup> The owner is precluded from *possessing* the occupied space and has *no power to exclude* the occupier. “The power to exclude has traditionally been considered one of the most treasured strands in an owner’s

376. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 426 (1982).

377. *Id.* at 427. See, e.g., *Pumpelly v. Green Bay Co.*, 80 U.S. (13 Wall.) 166, 181 (1872) (holding that a government authorized flooding of plaintiff’s property constituted a taking); *United States v. Causby*, 328 U.S. 256, 262 (1946) (observing physical invasions of airspace to be a taking); *Kaiser Aetna v. United States*, 444 U.S. 164, 180 (1979) (“[T]he imposition of the navigational servitude in this context will result in an actual physical invasion of the privately owned marina . . . . And even if the Government physically invades only an easement in property, it must nonetheless pay just compensation.”).

378. *Loretto*, 458 U.S. at 434-35 (quoting *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978)) (internal citation omitted).

379. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992).

380. *Loretto*, 458 U.S. at 435 (quoting *United States v. General Motors Corp.*, 323 U.S. 373, 378 (1945)).

381. *Id.*

bundle of property rights.<sup>382</sup> The owner is also denied power to control the use of her property, and is effectively precluded from transferring the occupied space, as “the permanent occupation of that space by a stranger will ordinarily empty the right of any value. . . .”<sup>383</sup> The *Loretto* Court considered the *permanence* of the occupation to be highly significant, “distinguish[ing] it from temporary limitations on the right to exclude,”<sup>384</sup> because these temporary limitations “do not absolutely dispossess the owner of his rights to use, and exclude others from, his property.”<sup>385</sup>

## 2. Deprivation of a “Core” Property Right

In many respects, this category is a broader generalization of the first; however, permanent physical invasion by the government does not “simply take a single ‘strand’ from the ‘bundle’ of property rights: it chops through the bundle, taking a slice of every strand.”<sup>386</sup> By a “core” property right, I envision a single strand in the bundle, the removal of which is enough to constitute a taking. The only such right recognized to date was found in *Hodel v. Irving*,<sup>387</sup> where the Court held that completely abolishing the right to pass on fee simple property at death is a per se taking.<sup>388</sup> In contrast, the Court has allowed a complete prohibition on the *sale* of personal property in *Andrus v. Allard*.<sup>389</sup> If *Allard* is to be distinguished, it must be that there was not prohibition on alienation,<sup>390</sup> but just on “one means of disposing” of them.<sup>391</sup> There the Court observed, “[T]he denial of one traditional property right does not always amount to a taking.”<sup>392</sup> Assuming *Allard* remains good law after *Hodel*,<sup>393</sup> there is no guide as to what sticks in the bundle of

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382. *Id.*

383. *Id.* at 436.

384. *Id.* at 435 n.12 (citing *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74 (1980)).

385. *Id.*

386. *Id.* at 435.

387. 481 U.S. 704 (1987).

388. *Id.* at 716-17.

[T]he regulation here amounts to virtually the abrogation of the right to pass on a certain type of property . . . to one’s heirs. In one form or another, the right to pass on property—to one’s family in particular—has been part of the Anglo-American legal system since feudal times. . . . [A] total abrogation of these rights cannot be upheld.

*Id.*

389. 444 U.S. 51, 67-68 (1979) (holding that a complete prohibition on the sale of eagle feathers did not constitute a taking).

390. The Court also noted that the challenged regulations “do not compel the surrender of the artifacts, and there is no physical invasion or restraint upon them.” *Allard*, 444 U.S. at 65.

391. *Id.*

392. *Id.*

393. *But see Hodel*, 481 U.S. at 719 (Scalia J., concurring) (noting that “the present statute, insofar as concerns the balance between rights taken and rights left untouched, is indistinguishable from the statute that was at issue in *Andrus v. Allard* . . . . Because that comparison is determinative of whether there has been a taking, in finding a taking today our decision effectively limits *Allard* to its facts”).

property rights are “core,” for even tradition is apparently not dispositive.

One might think that the right to exclude, being “one of the most treasured strands in an owner’s bundle of property rights,”<sup>394</sup> would be a “core” right. Were this so, it would have definite implications for intellectual property rights. However, as noted above, some limitations on the right to exclude are permissible. In *PruneYard* and in *Yee v. City of Escondido*, the Court found that significant limitations on the right to exclude were not takings. In *PruneYard*, the plaintiff sought to exclude the circulation of petitions in his shopping center, and was prohibited from doing so by the California Supreme Court’s construction of its state constitution.<sup>395</sup> Rejecting the takings claim, the United States Supreme Court acknowledged that “one of the essential sticks in the bundle of property rights is the right to exclude others,” and that there had “literally been a ‘taking’ of that right,”<sup>396</sup> but the Court concluded that “not every destruction or injury to property by governmental action has been held to be a ‘taking’ in the constitutional sense.”<sup>397</sup> Thus, the Court concluded that even after the California Supreme Court decision, “*PruneYard* may restrict expressive activity by adopting time, place, and manner regulations.”<sup>398</sup> The Court emphasized that the shopping center “is open to the public,”<sup>399</sup> and that under “these circumstances, the fact that they may have ‘physically invaded’ appellants’ property cannot be viewed as determinative.”<sup>400</sup> Similarly, in distinguishing *PruneYard*, Justice Marshall thought it significant that the case only presented temporary limitations, rather than an absolute loss of the right to exclude others.<sup>401</sup> So perhaps a *total* loss of the right to exclude, even if there was no permanent physical invasion, would be the taking of a “core” property right, within the meaning of the Fifth Amendment.

In *Yee v. City of Escondido*,<sup>402</sup> the Supreme Court rejected a takings claim where mobile home lot owners were restricted from “set[ting] rents or decid[ing] who their tenants will be.”<sup>403</sup> The plaintiffs argued that ordinances amounted to compelled physical occupation, however the Court denied this, saying “[b]ecause they voluntarily open their property to occupation by others, petitioners cannot assert a *per se* right to compensation

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394. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982).

395. *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74 (1980).

396. *Id.* at 82.

397. *Id.* (quoting *Armstrong v. United States*, 364 U.S. 40, 48 (1960)).

398. *Id.* at 83.

399. *Id.*

400. *Id.* at 84.

401. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 n.12 (1982).

402. 503 U.S. 519 (1992).

403. *Id.* at 526.

based on their inability to exclude particular individuals.”<sup>404</sup> The Court concluded that the land owners had not lost the “right to exclude,” because they could change the use of their land from a mobile home lot, and evict the tenants, as long as they gave six to twelve months notice.<sup>405</sup> Although the restriction on the right to exclude was significant, and was only a “regulation of petitioners’ use of their property, and thus does not amount to a *per se* taking.”<sup>406</sup> Apparently restrictions on the right to exclude do not violate a “core” property right, though, again, a *total deprivation* of the right to exclude might.

### 3. Linkage Conditions – Unconstitutional Conditions

The Takings Clause bars the government “from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole.”<sup>407</sup> Certain kinds of regulations impose requirements on property owners that they effectively deed some of their property rights for public use in exchange for the right to use their property in certain ways. Thus, there is a “linkage” or “extraction,” where the property owner must, for example, allow an easement, or pay fees in exchange for permission to build. In *Nollan v. California Coastal Commission*,<sup>408</sup> the Supreme Court held that “governmental authority to exact such a condition was circumscribed by the Fifth and Fourteenth Amendments.”<sup>409</sup> As noted in *Dolan v. City of Tigard*:

Under the well-settled doctrine of “unconstitutional conditions,” the government may not require a person to give up a constitutional right—here the right to receive just compensation when property is taken for public use—in exchange for a discretionary benefit conferred by the government where the benefit sought has little or no relationship to the property.<sup>410</sup>

Thus, if there is no “essential nexus” between the “legitimate state interest” and the condition exacted by the city on the owner’s property, then there is a taking.<sup>411</sup> Further, even if such a nexus exists, there must be a “rough proportionality” between the required condition and the effect of the

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404. *Id.* at 531.

405. *See id.* at 528 (citing Cal. Civ. Code Ann. § 798.56(g)).

406. *Id.* at 532.

407. *Dolan v. City of Tigard*, 512 U.S. 374, 384 (1994) (quoting *Armstrong v. United States*, 364 U.S. 40, 49 (1960)).

408. 483 U.S. 825 (1987).

409. *Dolan*, 512 U.S. at 385.

410. *Id.*

411. *Nollan*, 483 U.S. at 837; *see also Dolan*, 512 U.S. at 386.

use allowed by the government.<sup>412</sup> Such a “rough proportionality” does not require “precise mathematical calculation,” but at least “some sort of individualized determination.”<sup>413</sup>

#### 4. Regulatory Takings

In many ways, this final category is a catchall, which could be used to umbrella the proceeding categories. However, it is intended to address government regulations on the *use* of property. Generally, regulatory takings are analyzed under the three-factor test introduced in *Penn Central*. These factors are: (a) the character of the government action; (b) diminution in value of the property; and (c) the extent of interference with reasonable, investment-backed expectations.<sup>414</sup> These factors provide guidance, but must be viewed in light of the overall circumstances. As Justice Sutherland observed seventy-five years ago, “Regulations, the wisdom, necessity and validity of which, as applied to existing conditions, are so apparent that they are now uniformly sustained, a century ago, or even half a century ago, probably would have been rejected as arbitrary and oppressive.”<sup>415</sup> However, where “the State seeks to sustain regulation that deprives [property] of all economically beneficial use” it may only do so where the proscribed use interests were not part of the property right to begin with (i.e. one may be proscribed from creating a nuisance).<sup>416</sup> Therefore, regulations that prohibit all economically beneficial or viable use of property are per se takings of that property.<sup>417</sup> Although the exact contours of what it means to deprive property of all economically beneficial use are unclear,<sup>418</sup> such a deprivation

412. *Dolan*, 512 U.S. at 391. *Dolan* actually requires “rough proportionality” between the required condition and the “impact of the proposed development.” *Id.* Obviously, not all property rights involve building and development. The “impact” is really a way of measuring the effect of the use that is allowed. One might say that the impact is the effect of the benefit conferred by the government. However, in *Nollan*, Justice Scalia objected to the suggestion that exercise of an established property right (albeit one that had been previously restricted) was merely a “valuable Government benefit.” *Nollan*, 483 U.S. at 833 n.2. In dissent, Justice Brennan rejected this distinction. *See id.* at 860 n.10.

413. *Dolan*, 512 U.S. at 391.

414. *See Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978); *see also Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979); SINGER, *supra* note 374, at 1253.

415. *Euclid v. Ambler Realty Co.*, 272 U.S. 365, 387 (1926).

416. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1027 (1992).

417. *See id.* at 1029.

418. Indeed, in *Lucas*, the Court had the unusual circumstance where the state trial court “found a prohibition rendered Lucas’s property ‘valueless.’” *See id.* at 1007; *id.* at 1076 (Statement of Souter, J.) (suggesting dismissal of certiorari improvidently granted, as “the state trial court’s conclusion is highly questionable”). The Supreme Court recently addressed the question “whether the remaining permissible uses of regulated property are economically viable merely because the property retains a



does present a rare case. Most regulatory takings are considered under the three *Penn Central* factors.

*a. Character of Government Action*

“The ‘character of the government action’ concerns the issue of whether the regulation is more closely analogous to a physical invasion or seizure of a core property right” or rather “to a general regulatory program affecting numerous parcels and designed to protect the public from harm by adjusting the benefits and burdens of economic life to promote the common good.”<sup>419</sup> Regulations are less likely to be considered creating a taking if they are perceived as “part of the burden of common citizenship.”<sup>420</sup> Thus, *limitations* on property use to protect the community from harm, or that respond to externalities, rather than extractions of benefits, are less likely to be considered takings.<sup>421</sup> Similarly, regulations that achieve an “average reciprocity of advantage, meaning that those whose property interests are adversely affected by the regulation also benefit from it by the concomitant regulation of *other* people’s property rights” are less likely to be held to be takings.<sup>422</sup> Finally, a choice between incompatible property interests is also not generally regarded as a taking.<sup>423</sup> In contrast, a forced physical invasion, albeit temporary, the extraction of a benefit for the good of the community,<sup>424</sup> or a forced “redistribution of bargained-for contractual rights” rather than a “general regulatory program,”<sup>425</sup> is more likely to be held a taking. Thus, where the government seeks to achieve goals through regulation, which it is empowered to do through the “use of eminent domain,” it suggests the “practical equivalence” of “negative regulation and appropriation,” and hence a taking.<sup>426</sup>

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value greater than zero” in *Palazzolo v. Rhode Island*, 533 U.S. 606, (2001).

419. SINGER, *supra* note 374, at 1258. See also *Penn Central*, 438 U.S. at 124.

420. *Kimball Laundry Co. v. United States*, 338 U.S. 1, 5 (1949).

421. See SINGER, *supra* note 374, at 1258.

422. *Id.* (emphasis in original). See *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922) (distinguishing *Plymouth Coal Co. v. Pennsylvania*, 232 U.S. 531 (1914), as it involved “a requirement for the safety of employees invited into the mine, and secured an average reciprocity of advantage that has been recognized as a justification of various laws”); cf. *Penn Central*, 438 U.S. at 133-35.

423. See SINGER, *supra* note 374, at 1259; *Miller v. Schoene*, 276 U.S. 272 (1928) (upholding state statute requiring owners to cut down a large number of ornamental red cedar trees because they produced cedar rust fatal to apple trees cultivated nearby, even where there was no compensation for the value of the standing trees or loss in property value); *Penn Central*, 438 U.S. at 126 (“The [*Miller v. Schoene*] Court held that the State might properly make ‘a choice between the preservation of one class of property and that of the other . . . .’”).

424. The benefit/harm distinction, though perhaps “intuitive,” is often a difficult one, and has been criticized. See *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1024 (1992) (“[T]he distinction between ‘harm-preventing’ and ‘benefit-conferring’ regulation is often in the eye of the beholder.”); see also SINGER, *supra* note 374, at 1255-56.

425. SINGER, *supra* note 374, at 1258.

426. *Lucas*, 505 U.S. at 1019.

*b. Diminution in Value of Property*

Some diminution in value of property by regulations is certainly permissible because government “hardly could go on” if it had to pay “for every such change in the general law.”<sup>427</sup> At a minimum, a property owner is not always entitled to the highest and “most beneficial” use of her property.<sup>428</sup> Even “significantly diminish[ing] the value” of a property may not give rise to a taking.<sup>429</sup> Thus, in *Euclid v. Ambler Realty*,<sup>430</sup> which upheld the validity of zoning ordinances, the Court found that a zoning requirement resulting in a loss in market value of seventy-five percent was not a taking, and did not require compensation. Obviously, as it approaches a “total taking,” i.e. one hundred percent loss in value, then it becomes more like a taking.<sup>431</sup> Where that line is to be drawn is unclear.<sup>432</sup> The regulation is more likely to be considered a taking if it destroys or removes a large portion of the market value of the property or if it leaves little economically viable use. A taking could occur if something of independent value was taken from the property, even if the remaining property had significant value.<sup>433</sup> The takings analysis would focus on the removed property. A diminution in value is less likely to be a taking if what is lost was of little or no value, and what is left allows the owner a reasonable return on his investment, even if the value of the investment is greatly diminished.<sup>434</sup> Even a more substantial diminution is justified (perhaps even a 100% loss) if there is a “sufficiently strong

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427. *Pennsylvania Coal*, 260 U.S. at 413.

428. *Penn Central*, 438 U.S. at 125; see also *Euclid v. Ambler Realty Co.*, 272 U.S. 365 (1926); *Hadacheck v. Sebastian*, 239 U.S. 394 (1915).

429. *Penn Central*, 438 U.S. at 131.

430. 272 U.S. 365 (1926). See also *Hadacheck*, 239 U.S. 394 (holding 87½% diminution in value was not a taking).

431. See *Lucas*, 505 U.S. at 1030-31.

432. Lower courts have struggled with this issue. See, e.g., *Fla. Rock Indus., Inc. v. United States*, 18 F.3d 1560 (Fed. Cir. 1994) (discussing partial takings); *Loveladies Harbor, Inc. v. United States*, 28 F.3d 1171 (Fed. Cir. 1994) (discussing de minimis value). Leaving only a de minimis value is not sufficient. See, e.g., *Bowles v. United States*, 31 Fed. Cl. 37, 45 (1994) (Loren Smith, C.J.) (“[N]othing in the language of the Fifth Amendment compels a court to find a taking only when the Government divests the total ownership of the property,” the court reasoned. “[U]nder the guise of regulation [the] government cannot take from a property owner the core value of the property, leaving the owner with only a hollow deed.”). The Supreme Court recently wrestled with this very issue of line drawing in *Palazzolo v. Rhode Island*, 533 U.S. 606 (2001) without reaching any meaningful resolution.

433. Cf. *Laurin v. DeCarolus Constr. Co.*, 363 N.E.2d 675 (Mass. 1977) (involving breach of contract) (“Cutting a few trees on a timber tract, or taking a few hundred tons of coal from a mine, might not diminish the market value of the tract, or of the mine, and yet the value of the wood or coal, severed from the soil, might be considerable.”).

434. See *Hadacheck*, 239 U.S. at 408-09.

public interest; for example . . . to prevent a ‘noxious use’ and thereby to protect the public from harm.”<sup>435</sup>

*c. Interference with Reasonable Investment-Backed Expectations*

A regulation is more likely to be held a taking if a citizen has already invested substantially in reasonable reliance on an existing statutory or regulatory scheme; it is less likely to be ruled a taking if the regulation prevents the owner from realizing an expected benefit in the future.<sup>436</sup>

Some economic harms are to interests that are not “sufficiently bound up with the reasonable expectations of the claimant to constitute ‘property’ for Fifth Amendment purposes.”<sup>437</sup> In other cases, the property may well fall within the Fifth Amendment’s scope, but it is unreasonable for the property owner to believe they will be able to use their property in the desired way. Thus, zoning regulations restrict the manner in which property may be used, but such regulations are expected. “If, however, a developer spends substantial amounts of money on architectural and construction work for a particular project in reliance on existing zoning regulations and issuance of a building permit, courts are likely to hold retroactive application of changes in the zoning law invalid.”<sup>438</sup> Thus, a regulation is more likely to be held a taking if it interferes with an existing use of the property or with vested rights. In contrast, however, a regulation is less likely a taking if it merely imposes an opportunity loss, or if the property owner’s reliance on the continuation of prior law was unreasonable.<sup>439</sup> In a heavily regulated field (such as pharmaceuticals), the standard for finding *reasonableness* in investment-backed expectations is higher than in largely deregulated activities.

With this four-part analytical framework in mind, we may now consider how government infringement of intellectual property gives rise to a taking.

*B. Takings of Intellectual Property*

The analytical framework described above can be applied to takings of intellectual property; however, as a preliminary matter, we must consider to what extent IP is “property” for Fifth Amendment takings purposes. Then we may consider when or how it may be “taken” through infringement or

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435. SINGER, *supra* note 374, at 1259; *see Lucas*, 505 U.S. at 1022-25.

436. SINGER, *supra* note 374, at 1259.

437. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 125 (1978) (collecting cases).

438. SINGER, *supra* note 374, at 1260 (citing *Stone v. City of Wilton*, 331 N.W.2d 398 (Iowa 1983)).

439. *Id.*

other restrictions.

### 1. Is Intellectual Property Fifth Amendment “Property”?

The short (if not obvious) answer to the question “is intellectual property ‘property’ within the scope of the Fifth Amendment?” is “it depends”: it depends on the kinds of IP rights involved. In some cases the answer is an easy yes, others an easy no, and predictably, there may be forms of IP, both well-known and emergent, for which it is hard to answer this question. To some extent it may be nonsense to simply ask in the abstract, “is this property that can be taken” without examining the *context* of the alleged taking. Thus, the “property-ness” of the IP right may well depend on what is being done with it. Several scholars have begun to address this issue, and their insight provides a useful place to begin.<sup>440</sup>

Perhaps the most common property right in IP is the “right to exclude,” which is certainly present in patent, copyright, and trademark law. But is that enough? In some intellectual property (for example, patents), there is no right *other* than the right to exclude. The late Judge Rich of the U.S. Court of Appeals for the Federal Circuit proposed the following “pedagogical tool”:

Postulate that there is not now and never was a patent system. A person makes an invention. Assuming there is no law prohibiting it, can he make it? Can he use it? Can he sell it? Yes. *Without* a patent, he *has* all these rights. Now let’s write down . . . what the [patent] statute says the patent grants the inventor:

#### A. THE EXCLUSIVE RIGHT TO MAKE, USE, AND SELL

and write under it what rights he had without a patent:

#### B. THE RIGHT TO MAKE, USE, AND SELL

Now, let’s subtract B from A and see what the *patent* gave him

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440. E.g., Thomas F. Cotter, *Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?*, 50 FLA. L. REV. 529 (1998); John T. Cross, *Intellectual Property and the Eleventh Amendment After Seminole Tribe*, 47 DEPAUL L. REV. 519 (1998); Paul J. Heald & Michael L. Wells, *Remedies for the Misappropriation of Intellectual Property by State and Municipal Governments Before and After Seminole Tribe: The Eleventh Amendment and Other Immunity Doctrines*, 55 WASH. & LEE L. REV. 849 (1998).

## EXCLUSIVE

Every business man knows what it means to “have the exclusive” on something. What he gets from the patent—and all he gets—is a right to *exclude*. That’s the patent right.<sup>441</sup>

As noted by Professor Chisum, the “right to exclude, without the right to use, is somewhat peculiar to patent law (as well as the law of copyright and negative easements).”<sup>442</sup> Congress has specified, “[P]atents shall have the attributes of personal property.”<sup>443</sup> However, Congress’ “saying so” does not make it so when it comes to defining constitutional provisions. As we were forcefully reminded last Term, “Congress may not legislatively supersede [the Supreme Court’s] decisions interpreting and applying the Constitution.”<sup>444</sup> Thus, it is the Supreme Court’s definition of property under the Fifth Amendment that matters.<sup>445</sup>

As noted by Professors Heald and Wells, the Supreme Court “has defined ‘property’ very broadly in the Fifth Amendment context.”<sup>446</sup> Property “denote[s] the group of rights inhering in the citizen’s relation to the [thing owned], as the right to possess, use and dispose of it . . . . The constitutional provision is addressed to every sort of interest the citizen may

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441. DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 5 (1998) (quoting Columbia lecture notes of Judge Rich).

442. *Id.* The exclusionary right “is in a sense a negative right.” MERGES, ET. AL., *supra* note 315, at 134. A patent “does not automatically grant an affirmative right to do anything; patented pharmaceuticals, for instance, must still pass regulatory review at the Food and Drug Administration to be sold legally.” *Id.* Further, a patented invention “may itself be covered by a preexisting patent.” *Id.*

443. 35 U.S.C. § 261 (2000).

444. *Dickerson v. United States*, 530 U.S. 428, 437 (2000).

445. Despite the Court’s recent claims of exclusivity in defining constitutional provisions, *e.g.* *Dickerson*, *College Savings*, and *City of Boerne*, it is unclear that it is actually so here, though *College Savings* seems squarely on point. As recently as the *Lucas* decision, Justice Scalia reminded us that the Court’s taking jurisprudence “has traditionally been guided by the understandings of our citizens regarding the content of, and the State’s power over, the ‘bundle of rights’ that they acquire when they obtain title to property.” *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1027 (1992) (emphasis added). In other words, the Court looks to state law in determining a property right. Put differently, state law (albeit in the form background, common-law rules) defines the scope of some property interests, and thus the scope of the Takings Clause. That a state cannot substantially change these laws without providing compensation for eliminating a property right does not make it any less the state’s law that is doing the heavy lifting here. Justice Stewart puts it more squarely that “[p]roperty interests . . . are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.” *Regents v. Roth*, 408 U.S. 564, 577 (1972), *quoted in* *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001 (1984); *Webb’s Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 161 (1980); *Lucas*, 505 U.S. at 1003). If “understandings that stem from an independent source such as state law” determine what is “property” for purposes of the Takings Clause, then why is Congress any less equipped to be such an independent source? Given that patents and copyrights, as well as other forms of property, are federally defined, should not Congress’ definition automatically carry the day?

446. Heald & Wells, *supra* note 440, at 855.

possess.”<sup>447</sup> Further, the Court has recognized that the “hallmark of a protected property interest is the right to exclude others. That is ‘one of the most essential sticks in the bundle of rights that are commonly characterized as property.’”<sup>448</sup> In other words, the “overriding theme is exclusivity.”<sup>449</sup> Given this recognition, intellectual “property” that includes the right to exclude should qualify as “property,” while that which does not include the right is more suspect. It is no surprise that courts have repeatedly treated patents as property within the meaning of the Fifth Amendment.<sup>450</sup>

What then of copyright? Copyrights are described as granting certain exclusive rights, such as the right to reproduce, distribute, sell, perform, or display the copyrighted work.<sup>451</sup> However, a wrinkle is that unlike patent law, copyright does not give a “truly exclusive right to the work.”<sup>452</sup> Rather, the copyright holder “can only prevent others from copying or distributing *the original work*” or copies of the original.<sup>453</sup> As Professor Cross observes, independent creation of an identical work, though unlikely, is not itself

447. *United States v. Gen. Motors Corp.*, 323 U.S. 373, 378 (1945).

448. *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999) (quoting *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979)).

449. Cross, *supra* note 440, at 545. Professor Cross goes on to suggest a “rough definition of property for purposes of the takings restriction” as “an identifiable thing in which a person has a legally-protected expectation of exclusive possession and use.” *Id.* He claims patents, copyrights, and trademarks meet this definition. However, his “rough definition” is potentially too broad. There is no right to exclusive possession and use, as, in the case with patents, the owner may not be able to *use* his invention. Only to the extent that his invention can legally be used does he have exclusive rights to use. *See supra* notes 441-42 and accompanying text. Moreover, there may be “blocking patents” that prevent the patentee from using his invention, even if use is legal. *See supra* note 442.

450. *See, e.g., Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) (“That a patent is property, protected against appropriation both by individuals and by government, has been long settled.”). In *James v. Campbell*, 104 U.S. 356, 357-58 (1881), the Court reasoned,

That the Government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.

*Id.* at 357-58; *see also Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1571 (Fed. Cir. 1996) (“The government’s unlicensed use of a patented invention is properly viewed as a taking of property under the Fifth Amendment through the government’s exercise of its power of eminent domain.”). Similarly, courts have recognized that patents are “property” in the general sense and within the meaning of the Fourteenth Amendment. *See Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642 (1999) (“Patents . . . have long been considered a species of property. . . . As such, they are surely included within the ‘property’ of which no person may be deprived by a State without due process of law.”); *Schenck v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (“The patent right is but the right to exclude others, the very definition of ‘property.’”).

451. *See* 17 U.S.C. § 106 (2000) (“Exclusive Rights in Copyrighted Works”).

452. Cross, *supra* note 440, at 546.

453. *Id.* (emphasis added).

actionable.<sup>454</sup> Put more eloquently, “if by some magic a man who had never known it were to compose anew Keats’s *Ode on a Grecian Urn*, he would be an ‘author,’” entitled to copyright protection of his own, and not infringing any copyright Keats might have.<sup>455</sup> Yet, this loophole in exclusivity does not defeat copyright’s treatment as property. The copyright does protect *one’s own work*, and gives an exclusive right to copy, distribute, etc., the “fruits of one’s own intellectual labors.”<sup>456</sup> As the Second Circuit has observed, albeit in dicta, “[a]n interest in a copyright is a property right protected by the due process and just compensation clauses of the Constitution.”<sup>457</sup> This view is reinforced given that the Supreme Court *has* recognized as property, for the purposes of the Just Compensation Clause, more ephemeral IP rights.<sup>458</sup> It is also reinforced by Title 28, section 1498 of the United States Code, which creates a cause of action against the United States for federal government infringement of the copyright.<sup>459</sup> The Federal Circuit, which reviews appeals from the Court of Federal Claims, has suggested that section 1498, informed by the Takings Clause, is an expression of “the government . . . exercising its power of eminent domain.”<sup>460</sup>

Trademark law also presents its own unique issues in defining the scope of “property.” The Lanham Act and state trademark laws give rise to generally exclusive rights to a mark, but again not entirely.<sup>461</sup> The owner of a trademark cannot stop just anyone from using the same mark; instead, the law “only forbids others from using the mark when that use would result in customer confusion.”<sup>462</sup> Thus, often the same mark can be used, but in different geographic regions.<sup>463</sup> Even so, there is a significant scope of

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454. *See id.* at 546-47.

455. *Sheldon v. Metro-Goldwyn Pictures Corp.* 81 F.2d 49, 54 (2d Cir. 1936) (L. Hand, J.). Of course, any copyright that may have ever existed on Keats’s *Ode* would have long since expired, but the point is nonetheless clear.

456. Cross, *supra* note 440, at 547.

457. *Roth v. Pritikin*, 710 F.2d 934, 939 (2d Cir. 1983); *see also Lane v. First Nat’l Bank*, 871 F.2d 166, 174 (1st Cir. 1989) (finding that copyright “taken for public use” gives rise to “a constitutional right to just compensation”).

458. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 987 (1984) (holding that a “trade-secret property right” is “protected by the Taking Clause of the Fifth Amendment”). Trade secrets and other more ephemeral IP rights will be discussed below.

459. 28 U.S.C. § 1498(b). Section 1498 gives the patent or copyright owner an *exclusive* remedy in the United States Court of Federal Claims, rather than in a federal district court. *See id.* at (a) & (b). Section 1498 gives the patent or copyright owner less extensive remedies than normally available for infringement. “Reasonable and entire compensation” is available, but injunctions are not. *See id.*

460. CHISUM, ET. AL., *PRINCIPLES OF PATENT LAW* 1023 (1998) (citing *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1283 (Fed. Cir. 1988); *Chew v. California*, 893 F.2d 331, 336 (Fed. Cir. 1990)).

461. *See Lanham Act*, 15 U.S.C. §§ 1114, 1125(a) (2000).

462. Cross, *supra* note 440, at 546.

463. The Lanham Act gives nationwide rights to owners who register their marks with the Patent and Trademark Office. *See* 15 U.S.C. § 1115 (2000). However, as Professor Cross notes, many courts will not allow a trademark owner who does not do business in a given area to recover against

exclusivity carved out for the trademark holder. Despite this exclusivity, “trademark rights exist only in connection with the goodwill associated with the owner’s business operation.”<sup>464</sup> The upshot is that the deprivation of a trademark alone may not be a deprivation of property. As the trademark is “‘merely a protection for the good will’ . . . only if a regulation takes the owner’s *goodwill* as well would there be a taking.”<sup>465</sup> Here the nature of the property interest is best informed by the nature of the taking. For example, if the FDA merely prohibits the use of a trademark, it has not taken the underlying goodwill, and perhaps not taken anything.<sup>466</sup> However, if the FDA also begins using the mark, or authorizing others to use the mark, then it has taken the *exclusivity* away, and thus harms the underlying goodwill.<sup>467</sup> Once again the property interest is a “negative” one in exclusivity, not in use,<sup>468</sup> and should fall within the scope of the Takings Clause as such. Thus, it is unsurprising that in *College Savings*, the Court observed: “The Lanham Act may well contain provisions that protect constitutionally cognizable property interests—notably, its provisions dealing with infringement of trademarks, which are the ‘property’ of the owner because he can exclude others from using them.”<sup>469</sup>

In *Ruckelshaus v. Monsanto Co.*,<sup>470</sup> the court recognized that “a trade-secret property right” under state law “is protected by the Taking Clause of the Fifth Amendment.”<sup>471</sup> Trade secrets are “one of the weakest forms of intellectual property,” leading one commentator to observe that if trade secrets are protected, “then patents, copyrights, and trademarks must

a competitor using the mark only in that given area. See Cross, *supra* note 440, at 546 n.155 (citing *Dawn Donut Co. v. Hart’s Food Stores, Inc.*, 267 F.2d 358, 365 (2d Cir. 1959)).

464. Cross, *supra* note 440, at 545 n.152 (citing *United Drug Co. v. Theodore Rectanus Co.*, 248 U.S. 90, 97 (1918) (“There is no such thing as property in a trademark except as a right appurtenant to an established business or trade in connection with which the mark is employed.”); *Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 412 (1916) (“The redress that is accorded in trade-mark cases is based upon the party’s right to be protected in the good-will of a trade or business.”)).

465. *Dietary Supplements Regulations*, *supra* note 163, at 1042 (quoting *Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 414 (1916)) (emphasis added).

466. See *id.*; cf. *U.S. v. 70½ Dozen Bottles “666,” supra* note 163, at 91.

467. See *Dietary Supplements Regulations*, *supra* note 163, at 1042 (“This regulation will not allow one manufacturer to use another’s trademark or trade name . . . . Here, the government is not taking any trademark or trade name for its own use . . . .”).

468. See *supra* note 442.

469. *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999) (dicta) (citing *Kmart Corp. v. Cartier, Inc.*, 485 U.S. 176, 185-86 (1988) (“Trademark law, like contract law, confers private rights, which are themselves rights of exclusion. It grants the trademark owner a bundle of such rights.”)).

470. 467 U.S. 986 (1984).

471. *Id.* at 1003-04.



logically be protected as well.”<sup>472</sup> Patent, copyright, and trademark rights at least are “far more stable, certain, and property-like than trade secret law.”<sup>473</sup> A trade secret does not give a broad right to exclusivity, as another competitor may use the “secret” if she discovers it through non-surreptitious means.<sup>474</sup> However, there remains, as in copyright, a limited right to certain exclusive fruits of one’s own intellectual labors.<sup>475</sup> Trade secrets also “have many of the characteristics of more tangible forms of property” as they are assignable, can form the res of a trust, and pass on to the trustee in bankruptcy.<sup>476</sup> The “property-ness” of trade secrets is related to the notion that they are transferable rights. It is worth noting that Congress also recognizes the “proprietary” interest companies have in their trade secrets.<sup>477</sup>

Other forms of intellectual property are even more challenging to consider. Doctrinally related to trade secrets are rights of publicity, another form of intellectual property rights.<sup>478</sup> Such rights are both exclusive and transferable – thus prime candidates for Fifth Amendment protection. Yet, in *College Savings*, the Court held that right to be free of false advertising could not be considered a species of “property.”<sup>479</sup> It’s not entirely clear why. The court suggests that there is no right to exclude associated with “false advertising.” Yet, a prohibition on false advertising can be thought of

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472. Heald & Wells, *supra* note 440, at 856. Professors Heald and Wells contend that to “understand the breadth with which *Ruckelshaus* defines property, one must understand what a weak form of property a trade secret is.” *Id.* at 858. The RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39 (1995), defines trade secret as “any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.” There is only protection for such information if the acquisition by a another comes from discovering it through breach of contract or a trespass. There is no right to prevent someone from discovering the trade secret through, e.g. reverse engineering, independent creation, or the trade secret owner’s own carelessness. *See, e.g.,* *Schulenburg v. Signatrol, Inc.*, 212 N.E.2d 865 (Ill. 1965). Professor Tribe also suggests that *Ruckelshaus* should be read broadly. *See* LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* § 9-2, at 590-91 & n.11 (2d ed. 1988).

473. Heald & Wells, *supra* note 440, at 861.

474. *See* RESTATEMENT (THIRD) OF UNFAIR COMPETITION §§ 40, 43 (1995) (“‘Improper’ means of acquiring another’s trade secret under the rule stated in § 40 include theft, fraud, unauthorized interception of communications, inducement of or knowing participation in a breach of confidence . . . . Independent discovery and analysis of publicly available products or information are not improper means of acquisition.”).

475. *See supra* note 456 and accompanying text.

476. *Ruckelshaus*, 467 U.S. at 1002.

477. *See id.* (describing Congress’ treatment of trade secrets in the Federal Insecticide, Fungicide, and Rodenticide Act); *see also* Economic Espionage Act of 1996, 18 U.S.C. § 1831 (2000)) (providing protection for a wide range of information such as trade secrets). The Economic Espionage Act turns the misappropriation of trade secrets into a federal criminal offense. *Id.*

478. *See* Heald & Wells, *supra* note 440, at 862-63 (citing *Zacchini v. Scripps-Howard Broad. Co.*, 433 U.S. 562 (1977) and RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 46); *see also* *Calder v. Jones*, 465 U.S. 783 (1984); Joseph William Singer, *Publicity Rights and the Conflict of Laws: Tribal Court Jurisdiction in the Crazy Horse Case*, 41 S.D. L. REV. 1 (1996) (noting that rights of publicity are analogous to intellectual property rights).

479. *See* *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.* 527 U.S. 666, 673 (1999).

as the right to exclude anyone from speaking falsely about your product.<sup>480</sup> Certainly such a right is amorphous, and it is hard to see how it would be independently transferable. If Congress wanted to create such a *property* right, it is not entirely clear why it cannot, other than its harder to analogize to traditional property interests.<sup>481</sup>

In sum, though there are forms of intellectual property which may fall beyond the scope of “property” as expressed in the Takings Clause, they are the most abstract and amorphous of IP rights. Most forms of intellectual property, or at least those for which there is commercial interest and a market (patents, copyrights, trademarks, and even trade secrets), fall within the scope of Fifth Amendment’s Takings Clause as “property.” When or how they may be “taken” through infringement or other restrictions is the next topic.

## 2. When Intellectual Property is “Taken”

Not all restrictions on property amount to takings, and that is particularly true in the world of intellectual property, where the “property right” does not always include the right to “occupy” or “use” the property, but may *only* be the right to exclude. Nonetheless, the four-prong analytical framework detailed in Part IV.A provides a systematic approach to analyzing when government treatment of intellectual property rises to the level of a taking.

### a. “Physical” Invasions and “Core” Property Rights

At the outset the first category, “Physical Invasion of Property” seems inapplicable, after all, “intellectual property is intangible, it cannot, strictly speaking, be ‘possessed.’”<sup>482</sup> Yet, physical invasion is really just a specific form of confiscation. After all, “physical invasion” does not accurately describe a taking of chattel – the government does not so much “invade” the property as it *confiscates* it. If we recast the first category as “confiscation,” then it becomes more readily applicable to intangible property such as IP. Confiscation is where the government itself appropriates the IP owner’s intellectual property for its own use. For example, “when a state official makes unauthorized copies of computer software rather than buying it or uses patented biotechnology without obtaining permission” it is directly

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480. See *supra* Part III.B.

481. See *id.*; see also *supra* note 445.

482. Heald & Wells, *supra* note 440, at 866.

infringing in a confiscatory way.<sup>483</sup> *James v. Campbell*<sup>484</sup> supports this view. In the Court's assessment, the government could no more appropriate a patented invention "without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser . . . ."<sup>485</sup> It does not matter that the patent or other IP right still has useful value to the IP owner, just as it did not matter that the building owner in *Loretto* still had the vast bulk of his building to possess. Direct use (i.e., direct infringement) by the government should be a *per se* taking, just as much as confiscatory intrusion. The federal government is apparently aware of its obligation, and thus, section 1498 requires "reasonable and entire compensation" if the infringement is of a patent or copyright.<sup>486</sup>

Direct infringement presents a simple case of "eminent domain" taking.<sup>487</sup> The confiscatory/regulatory line begins to blur when the government uses IP but for a regulatory purpose.<sup>488</sup> In *Ruckelshaus*,<sup>489</sup> there is no question that the EPA can "use" trade secrets for the purpose of evaluating the manufacturer's product for approval – that would be akin to a license from the manufacturer. However, the Court also makes clear that it was permissible for Congress to require disclosure of "all health, safety, and environmental data" for use by the EPA.<sup>490</sup> If a distinction is to be drawn, it must be between competitive government use as confiscatory, and regulatory use – the latter being evaluated as a regulatory taking.

The "Core Property Right" approach also has great appeal for the intellectual property setting. As IP rights are in some ways more restricted than rights associated with "real property," the removal of a stick from the bundle may cut deeper into the quick. Presumably the right to devise an IP right would be "core" as in *Hodel*, but it might not be, as many IP rights are for limited duration (e.g., patents and copyrights). What is central to all of the IP rights explored in Part IV, is the right to exclude. In many cases, as Judge Rich's "formula" illustrates,<sup>491</sup> the only right associated with the intellectual asset is the right to exclude. Certainly any *total deprivation* of the "right to exclude" is a removal of not just a "core" property right, but of

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483. *Id.* at 867.

484. 104 U.S. 356 (1881).

485. *Id.* at 358.

486. 28 U.S.C. § 1498 (a) & (b) (2000).

487. *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1571 (1996), *vacated*, 520 U.S. 1183 (1997) ("The government's unlicensed use of a patented invention is properly viewed as a taking of property under the Fifth Amendment through the government's exercise of its power of eminent domain . . . .").

488. See Cotter, *supra* note 440, at 554-55.

489. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

490. See *id.* at 995-96.; see also 7 U.S.C. § 136h(d) (2000) (detailing disclosure requirements).

491. See *supra* text accompanying note 441.

the very essence of the intellectual property right.<sup>492</sup> More limited restrictions on the right to exclude are less clear. The whole “fair use” doctrine in copyright is about exceptions to the exclusive rights of the copyright holder.<sup>493</sup> Similarly, in patent law, there are equitable restrictions on the exclusive rights of patentees, and times where mandatory licenses may be the required remedy.<sup>494</sup> Most obviously, section 1498 only allows damages and fees,<sup>495</sup> not injunctions, for federal government infringements of patents or copyrights. Limited restrictions on the right to exclude will have to be examined either under a linkage or regulatory takings analysis, depending on the circumstances. Nonetheless, a total deprivation of the right to exclude (however limited that right may be defined) should be a *per se* taking.

*b. Linkage Conditions*

Many restrictions on intellectual property come in the form of “Linkage Conditions.” The government will grant the right to *use* the IP in a particular way, in exchange for an extraction or condition. The line between linkages and general regulations can become blurred. For example, one could say that the FDA will allow one to market one’s patented drug in exchange for going through the approval process, but that proves too much, and in any event involves giving up nothing inherent in the patent right. The better approach to linkages, rather than general regulatory programs is to focus on *quid pro quo* involving the rights associated with the IP asset, particularly the right to exclude. *Ruckelshaus v. Monsanto Co.* is directly on point. The Federal Insecticide, Fungicide, and Rodenticide Act [“FIFRA”] requires all pesticide manufacturers to register their products with the EPA.<sup>496</sup> In registering the product, manufacturers were required to submit

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492. See *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 148 F.3d 1343, 1349-50 (Fed. Cir. 1998) (“[A]t bottom, a patent is but the right to exclude others . . .”), *rev’d on sovereign immunity grounds, Florida Prepaid Postsecondary Education Expense Bd. v. College Savings Bank*, 527 U.S. 627 (1999); *Schenck v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (“The patent right is but the right to exclude others, the very definition of ‘property.’”).

493. See 17 U.S.C. § 107 (2000).

494. The “implied license” doctrine in patent law is simply a waiver of the patentee’s right to exclude. Such licenses “arise by acquiescence, by conduct, by equitable estoppel (estoppel in pais), or by legal estoppel.” *Wang Labs., Inc. v. Mitsubishi Elecs.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997). There is no requirement of “a formal finding of equitable estoppel as a prerequisite to a legal conclusion of implied license.” See *id.* at 1581.

495. See, e.g., *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1571-72 (Fed. Cir. 1996), *judgment vacated*, 520 U.S. 1183 (1997), *aff’d*, 140 F.3d 1470 (1998) (“Generally, the preferred manner of reasonably and entirely compensating the patent owner is to require the government to pay a reasonable royalty for its license as well as damages for its delay in paying the royalty.”).

496. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984).

data relating to the efficacy and safety of the products, as well as the chemical formulas of the pesticides.<sup>497</sup> In turn, following EPA verification and approval, the manufacturer is allowed to market the product. Thus far there is clearly no taking, just a regulation of use. The 1972 Amendments to FIFRA “included a provision that allowed EPA to consider data submitted by one applicant for registration in support of another application pertaining to a similar chemical.”<sup>498</sup> In return, the subsequent applicant must offer to compensate the original data provider, thus in effect “institut[ing] a mandatory data-license scheme.”<sup>499</sup> However, the 1972 Amendments provided that “trade secrets or commercial or financial information” were exempted from disclosure and “could not be considered at all by EPA to support another registration application unless the original submitter consented.”<sup>500</sup> Thus, the property-like intellectual assets of the manufacturer were protected. Following litigation resulting in broad application of the trade secret exemption to a great field of “health, safety, and environmental data,” preventing EPA from disclosing a majority of the data it had relied upon, FIFRA was again amended in 1978.<sup>501</sup> The 1978 Amendments provided a ten-year exclusivity period for data relating to pesticides registered after September 30, 1978.<sup>502</sup> It permitted EPA to use “[a]ll other data submitted after December 31, 1969 . . . in support of another application for 15 years after the original submission if the applicant offers to compensate the original submitter.”<sup>503</sup> Thus, all data from 1969 to 1978, regardless of whether it was a trade secret or not, was subject to a mandatory license. Under the 1978 regime, the IP owner was effectively required to give up exclusivity, as the EPA could use the data with any other potential registrants, in exchange for the opportunity to market its product. This is a clear linkage, though the Court did not approach it as such.

The *Ruckelshaus* Court examined the facts using the three *Penn Central* factors discussed in Part IV.A, principally focusing on the interference with “reasonable investment-backed expectations.”<sup>504</sup> The Court found that there was only a reasonable investment-backed expectation in secrecy with regard to data submitted between October 22, 1972, the effective date of the 1972 FIFRA Amendments and October 1, 1978, when the 1978 Amendments took place.<sup>505</sup> This was only because the government had created a reasonable

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497. *See id.* at 992.

498. *Id.*

499. *Id.*

500. *Id.* at 993.

501. *Id.* at 993-94; *see also supra* notes 196-213 and accompanying text.

502. *Ruckelshaus*, 467 U.S. at 994.

503. *Id.*

504. *See id.* at 1005.

505. *See id.* at 1010-14. Justice O'Connor, dissenting in part, would have found that data submitted prior to October 22, 1972 could effect a taking. *See id.* at 1021 (O'Connor, J., concurring in part and dissenting in part).

investment-backed expectation in the 1972 Amendments, by specifying that the EPA would not use trade secrets.<sup>506</sup> The government, through its promises, and through the type of regulatory system it put in place, could effectively set what expectations were *reasonable*. The court found that there would only be a taking of this property *without just compensation* if the negotiated/arbitrated license fee did not compensate the loss in market value of trade secret data.<sup>507</sup> If the fee did give just compensation, then there was no taking in violation of the Fifth Amendment. In Section C, below, I will suggest that this equitable approach could be applied in the *SmithKline* case.

By approaching *Ruckelshaus* through the lens of the *Penn Central* factors, the Court did not confront the real issue – that of linkage. The link was between EPA approval for use and non-exclusivity. Had the Court used a linkage analysis, it might have found greater protection for the pre-1972 data and perhaps less protection for the 1972-78 data. The linkage analysis asks, is there an “essential nexus” between the “legitimate state interest” and the condition exacted;<sup>508</sup> and if so, is there a “rough proportionality” between the required condition and the property use permitted by the government?<sup>509</sup> Here, the legitimate state interest is in the efficacy and safety (both human and environmental) of pesticides. The condition of submitting data to meet this purpose is easily justified, but what of allowing use of data to consider competitor’s products? The nexus is a weak one. The government interest could be met by requiring the competitors to generate their own data. Similarly, it can be met through compensation (as the FIFRA regime required). Even if the nexus requirement is met, then the “rough proportionality” requirement is also difficult to meet. The data is made generally available, not just kept and used by EPA, just on behalf of another competitor. Were the data used only in the service of approving pesticides, the very thing the data provider also seeks, the “proportionality” would be closer. Instead, competitors with access to the data may now use it for other purposes.

Interestingly, in *Nollan*, where the Supreme Court addressed linkages head-on, Justice Scalia distinguished *Ruckelshaus* as unrelated.<sup>510</sup> He argued that a right to register and sell pesticides was a “valuable government benefit” and *not* a property right, in contrast to the “right to build on one’s own property,” which “cannot remotely be described as a ‘government

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506. *See id.* at 1005-08.

507. *See id.* at 1013-14.

508. *Nollan v. Cal. Coastal Comm’n*, 483 U.S. 825, 837 (1987).

509. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994).

510. *Nollan*, 483 U.S. at 833 n.2.

benefit” even though “its exercise can be subject to legitimate permitting requirements.”<sup>511</sup> Thus, there was a “voluntary ‘exchange’” in *Ruckelshaus* that did not involve a restriction on one’s property rights.<sup>512</sup> In dissent, Justice Brennan contended the cases were indistinguishable: “Monsanto and the Nollans hold property whose use is subject to regulation; Monsanto may not sell its property without obtaining government approval and the Nollans may not build new development on their property without government approval.”<sup>513</sup> Justice Brennan concluded that “[o]btaining such approval is as much a ‘government benefit’ for the Nollans as it is for Monsanto.”<sup>514</sup> However, there is one distinction that gives Justice Scalia the better argument. There is no “right to use” in Monsanto’s IP right, unlike the Nollans’ “real property” interest. There is only the right to exclude.<sup>515</sup> Thus, while linkage analysis is attractive, it may not be entirely relevant. The government can always give something for something; only unconstitutional conditions are prohibited. Thus, in *Ruckelshaus*, the EPA is giving a right that the IP owner doesn’t have (the right to use) in exchange for something of value (the right to exclude). It is as if the government was simply buying the asset.

### c. Regulatory Takings

*Ruckelshaus* applied the *Penn Central* three-factor test to trade secrets, and thus demonstrates the test’s applicability to intellectual property.<sup>516</sup> Although the *Ruckelshaus* Court focused on the reasonableness of “investment-backed” expectations,<sup>517</sup> character of government action and diminution in value are also relevant. However, diminution in value is harder to conceptualize for those forms of property for which there is no *right to use*. Under FIFRA or the FDCA regimes, there can be no takings cause of action for forbidding the use of an intellectual asset on the grounds that it is ineffective or unsafe, because there is no right to use the IP asset. This makes regulatory takings analysis trickier for IP than for “real

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511. *Id.*

512. *Id.*

513. *Id.* at 860 n.10 (Brennan, J., dissenting).

514. *Id.*

515. From a theoretical vantage point, it might be that Monsanto *should* have a greater claim to use its property, *see id.* (citing JOHN LOCKE, THE SECOND TREATISE OF CIVIL GOVERNMENT 15-26 (E. Gough ed. 1947) (1698)), but that is not the law. A labor-desert theory of property rights might well give Monsanto a superior claim to use of its property, as the chemical formulae and data “only came into being by virtue of Monsanto’s efforts.” *Id.* However, courts applying the law of property, and more particularly intellectual property, while relying on such theories in dicta for justification, have never accepted a particular theory as dispositive. *See generally* Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988) (discussing the traditional theories of property and their application to intellectual goods).

516. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005 (1984).

517. *See id.* at 1005-08.

property.” The *Lucas* per se rule for a total deprivation of economically beneficial use cannot be applicable as such.<sup>518</sup> Dicta in *Lucas* even suggests that personal property (as opposed to land) may even be rendered worthless without causing a taking.<sup>519</sup> But this only recognizes that the settled expectations regarding personal property are less definitive than with land. However, many forms of IP are clearly defined, such as patents, copyrights, and trademarks.

Approaching regulatory takings as limitations on the right to use the IP asset simply proves too much when there is no right of use. Rather, “regulatory takings” should be approached from the vantage point of regulations that *alter* the property right that was conferred. For example, diminution in value is only relevant against the backdrop of legal use. If *use* is legally permissible, and the government restricts the ability to exclude, then there may be a relevant financial loss. Perhaps a total loss in value in such scenario could be considered a *Lucas*-esque per se taking. If the IP owner was prohibited from using her asset, but others were permitted to use it, there might be a total taking. Obviously diminution in value is tricky to apply and will be less important than the character of the government action and the interference with investment backed expectations.

The Hatch-Waxman Act provides a classic example of Congressional “regulation” in adjusting the property right of patents. The 1984 Act effectively eliminates a patentee’s right to exclude competitors from using the patentee’s patent for research and other uses “reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.”<sup>520</sup> It creates a new cause of action for the patentee when the competitor files an Abbreviated New Drug Application with the FDA, seeking approval of its own drug.<sup>521</sup> That cause of action also comes with an *automatic* thirty-month injunction against FDA approval, just for filing suit.<sup>522</sup> Despite this new cause of action, one fact

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518. The fact that an IP asset may be used by the government, for example, does not eliminate that asset’s economic viability. Heald & Wells, *supra* note 440, at 869-70. The very nature of IP is that one person’s use of the asset does not preclude another’s use. Even if the doors were flung open (as they are when a patent expires), the asset still has value to those using it. Therefore, a total deprivation of economically beneficial use will be rare. However, operating on the assumption that use of the asset is legal, there may be a market for it. That market would be eliminated if the right to exclude were eliminated. As suggested below, such a scenario might give rise to a total taking.

519. See *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1027-28 (1992) (“[I]n the case of personal property, by reason of the State’s traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless . . .”).

520. 35 U.S.C. § 271(e)(1) (2000).

521. See *id.* § 271(e)(2).

522. 21 U.S.C. § 355(j)(4)(B)(iii) (2000). Of course, *where* the patentee may file suit pursuant to



remains clear, actions now held exempt from infringement under 35 U.S.C. section 271(e)(1) would have infringed a valid patent under section 271(a) prior to the Hatch-Waxman Amendments.<sup>523</sup>

Opponents of the Amendments suggested that they raised serious constitutional issues of takings without just compensation.<sup>524</sup> The House Committee Report accompanying the Amendments identifies the *Penn Central* factors and suggests that as a “public program adjusting the benefits and burdens of economic life to promote the public good,”<sup>525</sup> the Amendments do not rise to the level of a taking. Rather, this is a case where there is government regulation with a “legitimate aim independent of its impact on the value of the property, an aim the government is ordinarily free to pursue under the police power.”<sup>526</sup> The Committee Report questions whether the *Roche* decision could create an investment backed expectation, as it was admittedly a case of first impression.<sup>527</sup> Further, even if “‘expectations’ are settled,” the Committee Report contends the character of the government interference is not that of a taking.<sup>528</sup> The patents still remain economically viable after the enactment of section 271(e)(1),<sup>529</sup> and the restriction on the right to exclude is only a limited one.<sup>530</sup> The public purpose requirement of the Takings Clause is easily satisfied. Although the most direct beneficiaries of the zone of non-infringement are other pharmaceutical manufacturers, the purpose is to improve public health

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this new cause of action is an altogether different issue. For a discussion of the situs of section 271(e) infringement and personal jurisdiction issues, see John C. O’Quinn, *There’s No Place Like Home: Finding Personal Jurisdiction in Abbreviated New Drug Application Patent Cases After Zeneca v. Mylan Pharmaceuticals*, 10 FED. CIR. B.J. 335 (2000).

523. See *Roche Prod, Inc. v. Bolar Pharms. Co.*, 733 F.2d 858, 861-63 (Fed. Cir. 1984).

524. See H.R. REP. NO. 98-857, pt. 2, at 7, 27-29 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2691, 2711-13.

525. *Id.* at 29 (citing *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978)).

526. *Heald & Wells*, *supra* note 440, at 870.

527. See H.R. REP. NO. 98-857, pt. 2 at 27-30 (discussing *Roche*, 733 F.2d 858); *id.* at n.39 (opinion of American Law Division, Library of Congress suggesting the Act expresses “a conclusion that *Roche* was wrongly decided, that Congress did not intend the word ‘uses’ in Sec. 271(a) to extend so broadly”). “Congress has previously legislated to change what it perceived to be incorrect judicial decisions and in so doing has adversely affected property rights of the prevailing side in those cases.” *Id.*

528. *Id.* at 30.

529. See *id.* at n.18.

530. See *id.* at n.19 (“The situation presented in [the Hatch-Waxman Act] does not result in the total extinguishment of the patent owner rights, because the patent owner still maintains a right to exclude others from the commercial marketplace.”). In contrast, Congress passed legislation in 1996 that precludes owners of patents on medical and surgical procedures from enforcing those patents. 35 U.S.C. § 287(c) (2000). This provision, enacted for public health reasons, completely eliminates the right to exclude. *Id.* Such a provision, applied retroactively would simply have to be a taking without compensation. However, section 287(c)(4) provides that “[t]his subsection shall not apply to any patent issued before the date of enactment of this subsection.” Thus, the patent property right was merely redefined on a going-forward basis, clearly within Congress’ power under the Patent and Copyright Clause.

through a quicker and greater availability of less expensive pharmaceuticals.<sup>531</sup>

The Report concludes that the nature of the interference is regulatory and should be expected in a highly regulated industry such as food and drugs.<sup>532</sup> It also rationalizes that the Hatch-Waxman Act compensates roughly the same group affected (albeit indirectly) through patent term extension.<sup>533</sup> Case law suggests that the shifting and balancing engaged in by Congress in the 1984 Act does not constitute a taking: “legislation readjusting rights and burdens is not unlawful solely because it upsets otherwise settled expectations.”<sup>534</sup> Here, there is no use of the “government’s power to isolate particular individuals for sacrifice to the general good” but a general, across the board, evenhanded balancing of benefits and burdens.<sup>535</sup> Further,

[T]he powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution, and as there are no restraints on its exercise, there can be no limitation of their right to modify them at their pleasure, so that they do not take away the rights of property in existing patents.<sup>536</sup>

Congress has not deprived the patentee of the general right to exclude, leaving only an empty shell of a patent right, but rather merely *modified* the patent right. The creation of a new cause of action under section 271(e), as well as the patent-term extension granted at the same time, support this conclusion. Applying the *Penn Central* factors reasonably shows the Hatch-Waxman Act not to be a taking.

The FDA’s “Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the

531. Cf. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1014-15 (1984) (observing that the required revealing and sharing of data would “eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly”).

532. See H.R. REP. NO. 98-857, pt. 2 at 30.

533. See *id.* at n.20.

It is important to note that most patent holders affected by [the Hatch-Waxman Act] will also receive a benefit from the bill in the form of patent term extension. This type of exchange of property interests was upheld by the Court in the *Grand Central* case [*Penn Central*], albeit in a different context.

*Id.*

534. *Pension Benefit Guar. Corp. v. R.A. Gray & Co.*, 467 U.S. 717, 729 (1984) (quoting *Fleming v. Rhodes*, 331 U.S. 100 (1947)).

535. *TRIBE*, *supra* note 472, § 9-6, at 605.

536. *Eldred v. Reno*, 239 F.3d 372, 380 (D.C. Cir. 2001), quoting *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843).

Body”<sup>537</sup> are another example of regulatory action which, if taken “too far” could amount to a taking. These regulations restrict the use of certain terms, “including terms that appear in some trademarks and trade names.”<sup>538</sup> The FDA rejects that a taking could occur without a deprivation of the underlying good will that gives value to a trademark.<sup>539</sup> The character of the action is regulatory rather than confiscatory. “Dietary supplement companies will not be precluded from using terms that imply a disease claim in their trademarks and trade names,” but if “they wish to continue using trademarks and trade names that imply a disease claim, they may do so, provided that they first meet the safety and efficacy standards and other regulatory requirements applicable to drugs . . . .”<sup>540</sup> Further, the regulations do not benefit some at the expense of others, “rather, all manufacturers will be precluded from using trademarks and trade names that contain an implied disease claim unless they have obtained new drug approval or health claim authorization.”<sup>541</sup> There is no right to *use* the mark, as it has “always been illegal to market dietary supplements or other foods with disease claims . . . .”<sup>542</sup> Regulations on the use of trademarks do not cause a loss of underlying goodwill, and thus the economic diminution is unclear, “even in cases where a trademark or trade name must be changed because new drug approval or health claim authorization cannot be obtained.”<sup>543</sup> Imposing regulations that require the trademark owner to spend money proving the claims is not the kind of economic impact that is categorized as a taking.<sup>544</sup> Finally, and as in *Ruckelshaus*, most significantly, the investment-backed expectations that might be abridged are unreasonable.

As noted in *Ruckelshaus*, “[i]n an industry that long has been the focus of great public concern and significant government regulation,” the possibility of modifications to the regulatory requirements is substantial.<sup>545</sup> With the high degree of historic regulation of food and drugs in the United States, even pre-dating the enactment of the FDCA in 1938,<sup>546</sup> investment-

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537. *Dietary Supplements Regulations*, *supra* note 163, at 1000.

538. *Id.* at 1041.

539. *See id.* at 1042.

540. *Id.*

541. *Id.*

542. *Id.* *See* *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1030 (1992) (“The use of [property] for what are now expressly prohibited purposes was *always* unlawful, and . . . it was open to the State at any point to make the implication of those background principles of . . . law explicit.”)

543. *Dietary Supplements Regulations*, *supra* note 163, at 1043.

544. *Atlas Corp. v. United States*, 895 F.2d 745, 756 (Fed. Cir. 1990), *cert. denied*, 498 U.S. 811 (1990) (“Requiring money to be spent is not a taking of property.”)

545. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1008 (1984) (quoting *FHA v. The Darlington, Inc.*, 358 U.S. 84, 91 (1958)). *See also* *Connolly, v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 227 (1986) (“Those who do business in the regulated field cannot object” when the regulatory scheme is “buttressed . . . to achieve the legislative end.”)

546. *See* Peter Barton Hutt, *A Historical Introduction*, 45 *FOOD DRUG COSM. L.J.* 17 (1990); HUTT & MERRILL, *supra* note 129, at 4-14. Even Roman civil law regulated the integrity of the food supply. Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 *ANN. REV.*

backed expectations that do not take into account the power of the state to regulate in the public interest are unreasonable.<sup>547</sup> Given that even the *Lucas* Court (a champion of property rights if there ever was one) has indicated that high expectations in *personal* property (i.e., not “real property”/land) are not reasonable,<sup>548</sup> these regulations past muster as not going too far.

Having seen how takings jurisprudence can be applied to intellectual property, Part IV.C applies it to the *SmithKline* case to determine whether the FDA’s actions (or the Second Circuit’s construction of the interplay between the Hatch-Waxman Act and the Copyright laws) can be considered an unconstitutional taking without just compensation.

### C. Was *SmithKline* a Taking?

When *SmithKline* sued *Watson Pharmaceuticals*, a *private*, non-state actor, it was for an act of copyright infringement.<sup>549</sup> However, *Watson*, in seeking approval to sell a competing generic nicotine gum product after *SmithKline*’s patent had expired, was “directed by the Food and Drug Administration . . . to use labeling almost identical to appellant’s copyrighted guide and tape.”<sup>550</sup> The FDA, in turn had “acted pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act . . . .”<sup>551</sup> The Second Circuit concluded that *Watson* “cannot be liable for copyright infringement because the Hatch-Waxman Amendments require generic drug products to use the same labeling, as was approved by the FDA for, and is used by the producer of the pioneer drug,” in this case the copyright holder.<sup>552</sup> In Part I, *supra*, I argued that the FDA interpretation was overbroad – that it was *not* in fact required by the Hatch-Waxman Act.<sup>553</sup> Nonetheless, let us assume that the FDA interpretation is *reasonable* or that the Hatch-Waxman Act *necessarily* trumps the copyright laws, as decided by Chief Judge Winter.<sup>554</sup> Then *SmithKline* has no claim against *Watson*;

NUTRITION I (1984), reprinted in HUTT & MERRILL, *supra* note 129, at 1.

547. See *Pace Res., Inc. v. Shrewsbury Township*, 808 F.2d 1023, 1033 (3d Cir. 1987), *cert. denied*, 483 U.S. 906 (1987).

548. See *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1027-28 (1992) (“[I]n the case of personal property, by reason of the State’s traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless . . .”).

549. See *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 22 (2d Cir. 2000)

550. *Id.*

551. *Id.*

552. *Id.* at 23.

553. See *supra* Part I.C.4.

554. See *SmithKline*, 211 F.3d at 28-29.

however, it may have a claim against the FDA. We can *reconceptualize* this case from one of *infringement* to one of a *taking* without just compensation. Here it is the FDA, acting pursuant to congressional authorization,<sup>555</sup> that is appropriating SmithKline's property and effectively giving it to competitors for their use. This section explores whether the FDA's actions under the Hatch-Waxman Act can be cast as a taking and whether a taking actually occurred.

Under the Second Circuit's interpretation, the Hatch-Waxman Act effectively serves as a partial amendment to the copyright laws, just as it is to the patent laws.<sup>556</sup> Owners of copyrights on drug labels may not exclude generic drug manufacturers with approved ANDAs from copying their labels.<sup>557</sup> This cuts at the core of the right to exclude, "the hallmark of a protected property interest."<sup>558</sup> This right is taken without any compensation, just or otherwise, and is given to competitors manufacturing a generic version of the *exact same drug*. Facially, a property right has been taken by the government. Applying the four-factored test discussed in Parts IV.A and B will indicate whether this taking falls within the scope of the Fifth Amendment's requirement of just compensation.

The action taken by the FDA, resulting in Watson being allowed to use SmithKline's copyright, is not akin to a confiscation of property, as the government is not appropriating the copyright for its own use nor is it prohibiting SmithKline from using it. Even though the copyright is effectively being appropriated for other companies to use, the weak public interest requirement is easily satisfied.<sup>559</sup> Similarly, even if the right to exclude is a "core" property right, the taking of which is a *per se* taking, here there has been no *total deprivation* of that right.<sup>560</sup> Rather, there has just been a restriction of the right to exclude under certain circumstances. As the Second Circuit noted:

We emphasize that we do not read the Hatch-Waxman Amendments to repeal other rights under the Copyright Act of copyright owners in SmithKline's circumstances. Even though such an owner cannot enforce its copyright against generic drug manufacturers who are required by the Hatch-Waxman Amendments to copy labeling and who do no more than that, it still retains a copyright, if otherwise

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555. Congress must at least implicitly authorize a "taking" by the Executive Branch in order for it to be lawful. See *Youngstown Sheet & Tube Co. v. Sawyer* 343 U.S. 579 (1952) ("The Steel Seizure Case"); *Dames & Moore v. Regan*, 453 U.S. 654 (1981).

556. See *SmithKline*, 211 F.3d at 28-29.

557. See *id.* at 29.

558. *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999).

559. See *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 242 (1984).

560. See *supra* notes 492-95 and accompanying text.

valid, in the label and might well pursue copyright claims against potential infringers in other circumstances, e.g., use of the copyrighted material in non-labeling advertisements.<sup>561</sup>

The loss of the right to exclude is narrow. SmithKline could still pursue infringers who do not have approved ANDAs, as well as those generics that use its label in advertising or other settings not required by the Hatch-Waxman Act.

One might think that linkage analysis would be appropriate, as the copyright owner must seek FDA approval of the drug and label in order to be able to market, and in exchange for approval, the Hatch-Waxman Act effectively allows the copyrighted label to be copied. In some sense, the facts are similar to those in *Ruckelshaus*. However, *Ruckelshaus* did not apply linkage analysis. Nor is it clear that the Hatch-Waxman Act actually creates a linkage. In the typical linkage case such as *Nollan* or *Dolan*, there is a quid pro quo: the property owner must give up some right for the specific requested government approval. In the *SmithKline* scenario, the right is removed statutorily, without respect to the specifics of approval. The FDA does not condition approvals on allowing the copyright to be used; rather, the very definition of the copyright grant is restricted in the case of ANDAs. The only aspect of this that appears to be a linkage is the fact that it applies just to labels of FDA approved drugs, because of the very nature of the ANDA provisions. Further, there is no property right to use the copyrighted label as labeling – the FDA must approve it – the granting of a copyright gives no special right to use.<sup>562</sup>

Even if the Hatch-Waxman Act were deemed to create a linkage with the copyright, an “essential nexus” between the “legitimate state interest” and the condition exacted by the FDA can be shown. The government has a strong interest in “facilitat[ing] the introduction of generic competitors once a pioneer drug’s patent term and exclusivity periods . . . ended by allowing the generic producer to piggy-back upon the pioneer producer’s successful FDA application.”<sup>563</sup> Such piggy-backing reduces the need for human testing, saves time and resources, and creates administrative ease in approval.<sup>564</sup> In a highly regulated field with an overall strong public health focus, the government interest in accurate information about drugs is great. Requiring generic manufacturers to avoid the copyright on a *label* when the patent on the underlying product has expired, would “also delay the

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561. *SmithKline*, 211 F.3d at 29.

562. See *supra* notes 520-23 and accompanying text.

563. *SmithKline*, 211 F.3d at 28.

564. See *id.*

introduction of the generic product without advancing public health and safety to any perceptible degree.”<sup>565</sup>

There is also a “rough proportionality” between the condition (allowing label copying) and the effect of the government approval of the pioneer drug. First, the FDA must approve the label itself.<sup>566</sup> The drug is only approved for uses on the label. A generic version, which may lawfully be approved under an ANDA may only be used for the same uses, thus the label should contain roughly the same things. Further, the Hatch-Waxman Act preserves a period of exclusivity for the pioneer based on the patent and other administrative exclusivity periods. Once that exclusivity has expired, only then can the copyright interest be trumped. Finally, as noted above, the Second Circuit’s reading of the Hatch-Waxman Act only repeals the limited right of the copyright owner to exclude competitors with approved ANDAs from copying its label for use as a label.<sup>567</sup> Thus, the extraction is narrow, focused, limited, and applies outside the scope of the exclusive right to market the underlying product which FDA approval grants the pioneer. It allows FDA to grant a *limited* exclusive period to the pioneer and keep it limited.

The real question is whether the FDA or Second Circuit interpretation of the Hatch-Waxman Act could effect a *regulatory* taking. The character of the government action cuts both ways. As it affects copyrights as well as patents, the Hatch-Waxman Act is a regulatory public program adjusting the benefits and burdens of economic life to promote the public good. As noted above, “Legislation readjusting rights and burdens is not unlawful solely because it upsets otherwise settled ‘expectations.’”<sup>568</sup> This would be expected to be particularly true in a heavily regulated industry where expectations are circumscribed by the pervasiveness of regulation. The Hatch-Waxman regime as a whole sought to create an average reciprocity of advantage, conferring some new rights on pioneer manufacturers in exchange for new limitations. Of course, copyrights were not explicitly considered in that balancing.<sup>569</sup> With respect to copyrights, there is no average reciprocity of advantage for the pioneers as they tend to be different companies from the generic manufacturers. If all pharmaceutical companies were involved in pioneer drug development and generic drug manufacturing, then there would be an average reciprocity of advantage, but that is not the case. In some respects this appears to be a use of the “government’s power to isolate particular individuals for sacrifice to the general good” rather than an evenhanded balancing of benefits and burdens.<sup>570</sup> Unlike the changes in

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565. *Id.*

566. *See id.* at 29 n.5.

567. *See id.* at 29.

568. *Pension Benefit Guar. Corp. v. R.A. Gray & Co.*, 467 U.S. 717, 731 (1984).

569. *See SmithKline*, 211 F.3d at 29.

570. *TRIBE*, *supra* note 472, § 9-6, at 605.

the patent laws, which created a new cause of action in section 271(e) while curtailing the scope of infringement under section 271(a), there was no balancing of the copyright interest. The copyright owner simply loses out, with nothing added in return.

Unlike many areas of IP, here there is clearly a diminution in value to the copyright owner. The ANDA provisions (and thus the Second Circuit's interpretation of the Hatch-Waxman Act curtailing the copyright laws) only apply to *approved* pioneer drugs with their *approved labels*. The generic competitor is only copying a drug that is already on the market. Further, the value of the copyright to the owner is really only against approved competitors, as non-approved marketing of drugs can be a criminal offense punishable by imprisonment.<sup>571</sup> Thus, the only value of the copyright is in excluding approved, legitimate competitors from using their label. As it will take the generic time to develop a different label that meets FDA approval, the copyright potentially extends the exclusivity of the drug, and thus is extremely valuable to the pioneer. Of course, the argument in response is that the pioneer was only to have the exclusivity provided by the patent or the administrative exclusivity period, and not to "piggy-back" on the copyright laws. The *copyright* itself has no value, only the underlying drug does. Thus, the pioneer cannot claim diminution in value from something outside the scope of the copyright. If anything, the diminution in value would be no more than the cost of developing the label, which in many cases is inconsequential compared to the costs (and profits) associated with the underlying drug.<sup>572</sup>

As in *Ruckelshaus*, the most important factor in determining whether the Hatch-Waxman Act could have effected a regulatory taking of certain copyrights is the degree to which it interferes with reasonable investment-backed expectations. SmithKline, for example, had already "invested substantially" in the Nicorette labeling (to the tune of "one million dollars"),<sup>573</sup> relying on the existing copyright laws as they were understood prior to the Second Circuit's decision. SmithKline had a significant investment in a creative guidebook and audiotape that "are an important part of the Nicorette product and an important component of the brand image that SmithKline has sought to create. The introduction into the market of virtually identical user guides and instructional tapes is likely to confuse consumers and threaten consumer goodwill."<sup>574</sup> This investment is similar to

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571. See 21 U.S.C. § 331 (2000) ("Prohibited Acts") & § 333 (2000) ("Penalties").

572. See *supra* note 83.

573. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 63 F. Supp. 2d 467, 469 (S.D.N.Y. 1999).

574. *Id.* at 471.



the scenario Professor Singer describes where a developer “spends substantial amounts of money on architectural and construction work for a particular project in reliance on existing zoning regulations” and the zoning laws are changed and retroactively applied.<sup>575</sup> Such retroactivity makes it more likely the regulation will be deemed a taking. However, here the substantial investment was not to get a copyright, but rather to obtain FDA approval of the pioneer drug in the first instance so that SmithKline could market Nicorette.<sup>576</sup> The copyrighted label itself has no value other than as associated with the product.<sup>577</sup> This view is reinforced by the fact that SmithKline did not register a copyright on the words and music on the audiotape until the “day when its exclusivity period for Nicorette expired.”<sup>578</sup>

Even if SmithKline had substantial investment-backed expectations in developing its copyright, these expectations may not be reasonable. If a property owner’s reliance on the continuation of prior law is unreasonable, there is no taking.<sup>579</sup> As noted above, given the high degree of regulation of foods and drugs in the United States, investment-backed expectations that do not take into account the power of the state to regulate in the public interest are unreasonable.<sup>580</sup> Although it is tempting to examine the government action strictly in the light of copyright law, we must remember that the Hatch-Waxman Act is focused on the pervasively regulated world of pharmaceuticals. Finally, it can be argued that SmithKline had no reasonable investment-backed expectation in extending its exclusivity period beyond that afforded by the patent laws and administrative exclusivity periods. This last point is perhaps dispositive. As Chief Judge Winter noted, “The purposes of the Hatch-Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA’s application of the ‘same’ labeling requirement.”<sup>581</sup> As the Hatch-Waxman provisions were “intended to facilitate the introduction of generic competitors once a pioneer drug’s patent term and exclusivity periods had ended by allowing the generic producer to piggy-back upon the pioneer producer’s successful FDA application,” it is simply unreasonable for a pioneer drug manufacturer to believe a copyright could be used to extend its exclusivity even for one

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575. SINGER, *supra* note 374, at 1260.

576. *See SmithKline*, 211 F.3d at 29 n.5.

577. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 63 F. Supp. 2d 467, 471 (S.D.N.Y. 1999) “[T]here is no separate market for the guides and tapes . . .”.

578. *SmithKline*, 211 F.3d at 23. SmithKline had, however, registered a federal copyright for the guidebook and the audiotape script nine months earlier. *See id.*

579. *See SINGER, supra* note 374, at 1260.

580. *See supra* notes 568-70 and accompanying text; *Pace Res., Inc. v. Shrewsbury Township*, 808 F.2d 1023, 1033 (3d Cir. 1987).

581. *SmithKline*, 211 F.3d at 28.

day.<sup>582</sup> Although the case is a close one, SmithKline should not prevail on a takings claim.<sup>583</sup>

Although SmithKline should not *win* a takings claim, it would have still been valuable for it to *raise* a takings claim. The doctrine of constitutional avoidance (interpreting statutes to avoid constitutional questions) counsels against interpreting the Hatch-Waxman Act in a manner that *could* be considered a taking, even if it did not actually rise to the level of a taking.<sup>584</sup> Thus, with the specter of a takings claim sitting in the background, the Second Circuit might have awarded SmithKline implied license fees or a reasonable royalty for the use of a copyright, rather than just eviscerating its cause of action.<sup>585</sup> By raising a takings claim, constitutional avoidance doctrine could have prevented SmithKline's copyright from simply being trumped by the FDA's treatment of the Hatch-Waxman Act. Thus, *SmithKline* demonstrates the value of raising a takings claim where the federal government appropriates or impinges on an intellectual property right.

582. *Id.*

583. It should also be noted that even if the Hatch-Waxman Act resulted in a taking of copyrights, that might only be true of those copyrights existing at the time it was enacted. Congress may, of course, prospectively alter the exclusive rights associated with copyrights, patents, and other forms of federally-defined intellectual property. As the Hatch-Waxman Act was enacted in 1984, and SmithKline did not develop the guide and tape until 1993 and did not seek federal copyright registration until 1998 and 1999, these would have been copyrights under the copyright laws as *amended sub silentio* by Hatch-Waxman. The complicating factor is that the Hatch-Waxman Act does not specifically address copyrights. Thus, it could be argued that the de facto amendment of the copyright laws did not occur until the FDA interpreted the Act in a manner requiring Watson to copy SmithKline's copyright. See *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214, 1999 WL 1243894, \*3-4 (S.D.N.Y. Dec. 22, 1999), *aff'd*, 211 F.3d 21 (S.D.N.Y. 2001). Under the later approach, SmithKline would have had its copyrights *before* the change in the copyright laws occurred, and thus would at least have a cause of action.

584. See, e.g., *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) ("Another rule of statutory construction, however, is pertinent here: where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress"); *N.L.R.B. v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 30 (1937) ("[A]s between two possible interpretations of a statute, by one of which it would be unconstitutional and by the other valid, our plain duty is to adopt that which will save the act"); *Murray v. The Charming Betsy*, 6 U.S. (2 Cranch) 64, 118 (1804) (Marshall, C.J.); see also *American Trucking Ass'ns, Inc. v. Browner*, 120 S. Ct. 2193 (2000) (granting certiorari on a question that would permit the Court to "avoid[] the constitutional nondelegation issue").

585. See *supra* Part I.C.3.

#### D. Takings by the States

A takings approach to government infringement may provide an independent remedy, or as highlighted by the previous Section, may serve to strengthen or buttress the intellectual property right claim through the doctrine of constitutional avoidance. A takings analysis of infringement may be especially potent when applied to acts of infringement by the states. As discussed in Part III.A, the Supreme Court's sovereign immunity jurisprudence has rendered the states immune from suits for infringement in federal court. This result is interesting, if not peculiar, given the current majority's vigorous protection of property rights in other contexts.<sup>586</sup> In *Florida Prepaid*, the Court was able to duck the issue of whether the state had "taken" the plaintiff's patent. Chief Justice Rehnquist observed:

There is no suggestion in the language of the statute itself, or in the House or Senate Reports of the bill which became the statute, that Congress had in mind the Just Compensation Clause of the Fifth Amendment. Since Congress was so explicit about invoking its authority under Article I and its authority to prevent a State from depriving a person of property without due process of law under the Fourteenth Amendment, we think this omission precludes consideration of the Just Compensation Clause as a basis for the Patent Remedy Act.<sup>587</sup>

As the Court was simply examining the constitutionality of the Patent Remedy Act, it was excused from the broader question of whether the state had violated the Just Compensation component of the Takings Clause. Moreover, because the legislative record did not examine the existence or adequacy of state remedies, much less demonstrate widespread state infringement, some of which would not even rise to the level of a constitutional violation, the Court was able to comfort itself in blissful ignorance of any state takings without just compensation.<sup>588</sup> Resting assured that the states were not committing a "widespread and persisting deprivation" of constitutional property rights,<sup>589</sup> the Rehnquist Court was able to further its jurisprudential project of protecting states' rights without confronting the limits imposed by its other main jurisprudential project: the protection of property rights.

This Section examines a key unanswered question from *Florida Prepaid*: what currency does the Just Compensation Clause provide in

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586. See *supra* notes 263-65 and accompanying text.

587. Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 642 n.7 (1999).

588. See *id.* at 641-44.

589. *Id.* at 645 (quoting *City of Boerne v. Flores*, 521 U.S. 507, 526 (1997)).

questions of state IP infringement?<sup>590</sup> We will explore the clash between states' rights and property rights head on and consider whether the Just Compensation Clause, as applied through the Fourteenth Amendment, provides a path around *Florida Prepaid*, *Alden*, and sovereign immunity generally, into state or federal court for state acts of infringement.

The Chief Justice's opinion in *Florida Prepaid* could be read to suggest that Congress can no more abridge state sovereign immunity pursuant to the Just Compensation Clause than it could any other constitutional provision incorporated to apply to the states through the Fourteenth Amendment.<sup>591</sup> The language he used to describe the *remedial* aspects of Congress' power under Section Five of the Fourteenth Amendment, could be read to require a

590. The other unanswered question from *Florida Prepaid* is what constitutes the *state* for purposes of sovereign immunity? See *id.* at 633 n3. Although space does not permit me to explore that question here in detail, it is an issue ripe for extensive litigation. For example, one can imagine a return to a "traditional" or "integral" state function approach, such as in *National League of Cities v. Usery*, 426 U.S. 833 (1976), for determining whether the state is behaving as state qua state. Although *National League of Cities* was overruled by *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985), after *Seminole Tribe* and its progeny the viability of *Garcia* itself is questionable. Nonetheless, *Garcia* was correct to criticize the *National League of Cities* standard as "unworkable." See *Garcia*, 469 U.S. at 546-47.

A better standard for determining what is the *state* for sovereign immunity purposes might be a "market participant" approach. Rather than puzzle over whether a particular function is traditionally or integrally that of a state, instead a court would consider whether the state is competing with private actors in the market. If not, then it can be assumed to be acting in its sovereign or regulatory capacity. Such a "market participant" distinction is not novel — it can be found in Commerce Clause jurisprudence. See *Reeves, Inc. v. Stake*, 447 U.S. 429, 436-37 (1980) (holding that the distinction between "States as market participants and States as market regulators makes good sense and sound law" and noting that "the commerce clause was directed, as an historical matter only at regulatory and taxing actions taken by states in their sovereign capacity" and that there was nothing indicating a "constitutional plan to limit the ability of the States themselves to operate freely in the free market"); *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976) (distinguishing between state as regulator and state as participating in the market for Commerce Clause purposes); see also LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* § 6-11, at 1088-95 (3d. ed. 2000). A similar distinction is found in antitrust law under the state action doctrine. See *Parker v. Brown*, 317 U.S. 341 (1943) (distinguishing between a state authorizing private parties to act anticompetitively and a state itself regulating commerce); AREEDA & KAPLOW, *supra* note 88, ¶ 165, at 128-34; Steven Semeraro, *Demystifying Antitrust State Action Doctrine*, 24 HARV. J.L. & PUB. POL'Y 203, 209-12, 265-70 (2000).

Although the distinction between state qua state and state as market participant may be a difficult one to draw at times, it is a distinction the courts are already familiar with. Applying the distinction in *Florida Prepaid*, the Florida Prepaid program would probably be considered in competition with other annuity contract plans for financing future college expenses, such as that offered by the College Savings Bank. See *Florida Prepaid*, 527 U.S. at 631 ("Florida Prepaid Postsecondary Education Expenses Board . . . is an entity created by the State of Florida that administers similar tuition prepayments contracts [to those of College Savings Bank].")

591. See, e.g., RICHARD H. FALLON, DANIEL J. MELTZER, & DAVID L. SHAPIRO, *HART AND WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM* 115 (4th ed. Supp. 2000); Daniel J. Meltzer, Statement before the House Subcommittee on Courts and Intellectual Property, at n.22 (July 27, 2000), available at <http://www.house.gov/judiciary/melt0727.htm>.

“history of ‘widespread and persisting deprivation of constitutional rights’” even when Congress is enforcing the Just Compensation Clause.<sup>592</sup> However, the Supreme Court has rejected the argument that the Fifth Amendment’s Takings Clause is “only a limitation on the power of the Government to act, not a remedial provision,” instead finding that “it is the Constitution that dictates the remedy for interference with property rights amounting to a taking.”<sup>593</sup> Each act of taking without just compensation is a constitutional violation requiring a remedy. Thus, “[a] sovereign immunity defense [] may not be available against a takings challenge, because the Court has suggested, although it has not clearly held, that the Fifth Amendment’s Takings Clause trumps state (as well as federal) sovereign immunity.”<sup>594</sup>

Indeed, the Supreme Court has described the Takings Clause as “self-executing.”<sup>595</sup> Further, the Court has observed that “in the event of a taking, the compensation remedy is required by *the Constitution*” itself.<sup>596</sup> *First English* suggests that the Takings Clause, and its requirement of just compensation, even applied to the states operates “*of its own force*, furnish[ing] a basis for a court to award money damages against the government.”<sup>597</sup> Thus, Congress need not legislatively attempt to abrogate state sovereign immunity in order for a state to be sued for a taking without just compensation in state, and perhaps federal, court.

At a minimum, the “self-executing” nature of the Just Compensation requirement of the Takings Clause suggests that a state may not close the doors of its courts to takings claims. For example, in *Reich v. Collins*,<sup>598</sup> a state court action for a state tax refund, the Court held that the “Constitution itself” required the state to provide the remedy it has promised.<sup>599</sup> Similarly, in *McKesson Corp. v. Division of ABT*,<sup>600</sup> the Supreme Court held unanimously that if a state requires taxpayers to pay first and obtain review of a tax’s validity later, the Due Process Clause requires the state to provide a meaningful opportunity to secure postpayment relief.<sup>601</sup> In these cases as well as *Ward v. Love County*,<sup>602</sup> the remedy may have been required because of the Takings Clause, as applied to the states through the Due Process

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592. *Florida Prepaid*, 527 U.S. at 642 n.7 (same).

593. *First English Evangelical Lutheran Church v. Los Angeles County*, 482 U.S. 304, 316 n.9 (1987).

594. 1 TRIBE, *supra* note 590, § 6-38, at 1272-73.

595. *United States v. Clarke*, 445 U.S. 253, 257 (1980).

596. *First English*, 482 U.S. at 316 (emphasis added).

597. *Id.* at 316 n.9 (quoting Solicitor General’s brief) (emphasis added).

598. 513 U.S. 106 (1994).

599. *Id.* at 109.

600. 496 U.S. 18 (1990).

601. *See id.* at 36-37.

602. 253 U.S. 17 (1920) (requiring tax refund).

Clause of the Fourteenth Amendment.<sup>603</sup> Unlike *Alden v. Maine*,<sup>604</sup> in which the Court held that Congress may not subject non-consenting states to private suits in their own state courts,<sup>605</sup> here, it is the Constitution itself that flings wide the doors to a state court. Even the *Florida Prepaid* Court recognized that “where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent” a constitutional violation may occur.<sup>606</sup> Thus, in the case of takings of intellectual property, just as for “real” property, the state must provide a mechanism for adjudicating claims and remedying with just compensation.<sup>607</sup>

Professor Tribe has suggested that perhaps “because the Constitution itself prescribes ‘just compensation’ as the remedy for a taking, a federal court must have the power to award damages against even an unconsenting state under a takings claim.”<sup>608</sup> The Constitution itself can give rise to a cause of action.<sup>609</sup> And it is generally “presume[d] that justiciable constitutional rights are to be enforced through the courts.”<sup>610</sup> Further, Article III extends the “judicial Power” of the United States “to all Cases, in Law and Equity, arising under this Constitution”<sup>611</sup> and Congress has conferred this jurisdiction on the federal district courts.<sup>612</sup> Thus, it would

603. See RICHARD H. FALLON, DANIEL J. MELTZER, & DAVID L. SHAPIRO, HART AND WECHSLER’S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 849-50 (1996).

604. 527 U.S. 706 (1999).

605. See *id.* at 732.

606. Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 643 (1999). Cf. *Hudson v. Palmer*, 468 U.S. 517, 539 (1984) (O’Connor, J., concurring) (“[I]n challenging a property deprivation, the claimant must either avail himself of the remedies guaranteed by state law or prove that the available remedies are inadequate.”).

607. See, e.g., *Jacobs Wind Elec. Co. v. Dep’t of Transp.*, 626 So. 2d 1333, 1337 (Fla. 1993) (holding “a patent holder not preempted under federal law may assert takings and conversion claims in state court”). The Florida Supreme Court also observed that federal preemption over claims “arising under” the patent and copyright laws did not “bar state jurisdiction when the complaint relies on ‘reasons completely unrelated to the provisions or purposes of [the patent laws]’” such as the federal and state constitutional prohibitions on the state’s taking of private property without due process or just compensation. *Id.* at 1335. Cf. *Chew v. California*, 893 F.2d 331, 336 (Fed. Cir. 1990) (pre-Patent Remedy Act case) (holding that “a patent infringement suit is not the appropriate legal remedy for vindicating a [state] ‘takings’ claim” and noting this decision “simply forecloses one avenue of recourse – the specific relief for infringement of patent rights otherwise provided by federal statute” but suggesting that a state remedy would necessarily be available).

608. 1 TRIBE, *supra* note 590, at 1273 n.18.

609. E.g. *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971) (rejecting the argument that “the Fourth Amendment serves only as a limitation on federal defenses to a state law claim and not as an independent limitation upon the exercise of federal power”).

610. *Davis v. Passman*, 442 U.S. 228, 241-44 (1979).

611. U.S. CONST. art. III, § 2.

612. 28 U.S.C. § 1331 (“The district courts shall have original jurisdiction of all civil actions arising under the Constitution . . .”).

appear that a plaintiff with a takings claim against a state could bring suit in a federal court. Nonetheless, *Williamson County Regional Planning Commission v. Hamilton Bank*<sup>613</sup> is read to hold that “a state that takes private property does not violate the Takings Clause until it refuses to pay the owner just compensation.”<sup>614</sup> Thus, “the assertion of a takings claim against a state in federal court is not ripe until the state has first denied compensation in a state inverse-condemnation suit.”<sup>615</sup> Therefore, “as long as a state renders itself amenable to inverse condemnation actions in its own courts, a property owner . . . cannot assert that the state has taken that property without just compensation until the state court rejects his claim,”<sup>616</sup> and there is no cause of action suitable for a federal court under the Constitution. Dicta in *Florida Prepaid* would appear to support this view as applied to intellectual property. As noted above, the Court observed that “only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result.”<sup>617</sup>

*Williamson County* suggests that with respect to intellectual property, as well as real property, the state must open its courts’ doors, or the federal doors will be open to the IP owner.<sup>618</sup> The infringing state cannot altogether avoid liability, though it may force the IP owner to use takings procedures rather than the law of infringement.<sup>619</sup> However, others suggest that if *Williamson County* is just a prudential holding, rather than a constitutional interpretation, Congress can alter it.<sup>620</sup> In some sense, *Williamson County*

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613. 473 U.S. 172 (1985).

614. Christina Bohannon & Thomas F. Cotter, *When the State Steals Ideas: Is the Abrogation of State Sovereign Immunity from Federal Infringement Claims Constitutional in Light of Seminole Tribe?*, 67 *FORDHAM L. REV.* 1435, 1460 (1999). “*Williamson County*’s apparent holding [is] that a violation of the Fifth Amendment does not occur until the state has refused compensation.” *Id.* at 1474.

615. *Id.* See also Daniel J. Meltzer, Statement before the House Subcommittee on Courts and Intellectual Property, at n.22 (July 27, 2000), available at <http://www.house.gov/judiciary/melt0727.htm>.

616. Bohannon & Cotter, *supra* note 614, at 1470-71.

617. Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 643 (1999). See also Parratt v. Taylor, 451 U.S. 527 (1981); Hudson v. Palmer, 468 U.S. 517, 539 (1984) (O’Connor, J., concurring) (“[I]n challenging a property deprivation, the claimant must either avail himself of the remedies guaranteed by state law or prove that the available remedies are inadequate. . . . When adequate remedies are provided and followed, no . . . deprivation of property without due process can result.”).

618. See *Williamson County*, 473 U.S. at 195.

619. *Id.*

620. See Max Kidalov & Richard H. Seamon, *The Missing Pieces of the Debate over Federal Property Rights Legislation*, 27 *HASTINGS CONST. L.Q.* 1 (1999) (suggesting Congress may eliminate prudential justiciability rules perhaps such as ripeness, though not exhaustion); Private Property Rights Implementation Act of 2000, H.R. 2372, 106th Cong. (March 20, 2000) (providing for ripeness of a cause of action for a deprivation of a property right upon the action by a state actor causing actual and concrete injury); cf. *Suitum v. Tahoe Reg’l Planning Agency*, 520 U.S. 725, 734 n.7 (1997) (noting that “ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction”).

just prescribes an act of abstention – allowing the state to resolve the alleged taking before permitting a federal court to engage in constitutional review of the state’s action.<sup>621</sup> In fact, the venerable *Home Telephone* case,<sup>622</sup> which is directly on point, affirms this view.

In *Home Telephone* the plaintiff telephone company alleged that phone rates were fixed “so unreasonably low that their enforcement would bring about the confiscation of the property of the corporation, and hence the ordinance was repugnant to the due process clause of the 14<sup>th</sup> Amendment.”<sup>623</sup> The state argued that because the actions “were presumptively repugnant to the state Constitution, such could not be treated as acts of the state within the Fourteenth Amendment, and hence no power existed in a Federal court to consider the subject” that is “until, by final action of an appropriate state court, it was decided that such acts were authorized by the state, and were therefore not repugnant to the state Constitution.”<sup>624</sup> The Supreme Court, per Chief Justice White, rejected this view, noting that it would “attach to the exercise of Federal judicial power under all circumstances” and “hence render impossible the performance of the duty with which the Federal courts are charged under the Constitution.”<sup>625</sup> The Court rejected the “paralysis” that would “inevitably ensue” if the ability to exercise federal judicial power “would depend on the ultimate determination of the state court, and would therefore require a stay of all action to await such determination.”<sup>626</sup> The Supreme Court refused to create a situation in which the “Federal courts . . . would have to await the determination of a state court as to the operation of the Constitution of the United States,” thus “caus[ing] the state courts to become the primary source for applying and enforcing the Constitution of the United States in all cases covered by the Fourteenth Amendment.”<sup>627</sup> Instead, the scope of federal judicial power under the “reach of the [Fourteenth] Amendment is . . . coextensive with any exercise by a State of power, in whatever form exerted.”<sup>628</sup>

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621. *Cf. R.R. Comm’n of Texas v. Pullman Co.*, 312 U.S. 496 (1941).

622. *Home Tel. & Tel. Co. v. City of Los Angeles*, 227 U.S. 278 (1913).

623. *Id.* at 281.

624. *Id.* at 282.

625. *Id.* at 284.

626. *Id.*

627. *Id.* at 285.

628. *Id.* at 287. A similar interpretation was given to 42 U.S.C. § 1983 in *Monroe v. Pape*, 365 U.S. 167 (1961), which rejected the argument that federal courts could not apply § 1983 if state courts allow a remedy for the alleged constitutional violation.



*Home Telephone* would suggest that federal courts could consider claims of takings in violation of the Fifth and Fourteenth Amendments even before a state tribunal has adjudicated the matter. *Williamson County* must then be prudential, and as such amendable by Congress. Congress can create a cause of action for *takings* of intellectual property by the states, which may be brought in federal court. In the case of patents, Congress could route appellate review of state takings claims brought in federal district court to the United States Court of Appeals for the Federal Circuit, hence preserving the goal of uniformity in the patent laws.<sup>629</sup> Thus, the Takings Clause provides a means for ensuring greater protection of intellectual property from state appropriation and infringement.

## V. CONCLUSION

The Second Circuit's decision in *SmithKline* is a stark reminder that vigilance is the price for preserving intellectual property rights. Courts stand ready to trade these rights away for other, often worthy, goals such as administrative deference and the protection of states rights. The Supreme Court's decisions in *Florida Prepaid* and *College Savings* as well as other judicial decisions have led to a curtailment of federal protection of intellectual property, particularly where the states are involved. Despite these defeats for IP, there is a means for overcoming some of the recent judicially-enacted obstacles to protecting intellectual property. That means is the Takings Clause of the Fifth Amendment, applied to the states through the Fourteenth Amendment. In some cases government infringement is an actionable taking. Yet, even where government action limiting IP rights does not rise to the level of a taking, the Takings Clause can be used to protect IP. The overly broad decision of the Second Circuit in *SmithKline*, effectively wiping out all meaningful copyright protection for pioneer drug manufacturers, might have been narrowed had the court considered the potential takings ramification of its decision.

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629. See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 644 (1999) (noting concerns over state remedies being "less convenient than federal remedies" and "undermin[ing] the uniformity of patent law"); *id.* at 2211 (Stevens, J., dissenting) (commenting on the "principle that undergirds all aspects of our patent system: national uniformity"). Professor Meltzer suggests inventive ways to have *state* adjudications of patent claims routed to the Federal Circuit, either through appeal from the highest state court, appeal from the state trial court, or a certification to the Federal Circuit. Daniel J. Meltzer, Statement before the House Subcommittee on Courts and Intellectual Property, at n.22 (July 27, 2000), available at <http://www.house.gov/judiciary/melt0727.htm>. Such heroic efforts to preserve uniformity in the patent system would be unnecessary if a federal takings action for patents were available, as patentees would likely choose the federal forum. Furthermore, Congress presumably could make the federal takings action an exclusive remedy, just as federal courts have exclusive jurisdiction over claims of patent and copyright infringement.

With the Takings Clause moved from the distant background to the forefront of intellectual property protection, courts will be guided by the principle of constitutional avoidance, and thus will seek more equitable resolutions, rather than simply allowing IP rights to be trumped. Considerations of “just compensation” could have led the *SmithKline* court to provide some financial remedy to the copyright owner, even though it might have withheld injunctive relief. Finally, the self-executing nature of the Takings Clause suggests an effective remedy for state infringement of intellectual property rights. States cannot hide behind sovereign immunity when they infringe. At a minimum, they must provide a state forum to adjudicate takings claims and dispense just compensation. Moreover, the Takings Clause provides a self-executing abrogation of state sovereign immunity that should allow Congress to create a federal remedy.

The time has come to recognize the scope of intellectual property rights and the protection provided for these rights by the Constitution – including the Takings Clause. Only by discerning the full applicability of the Takings Clause to IP rights and seizing upon these protections can federal and state agencies be held accountable to the laws that protect intellectual property. *SmithKline* represents a lost opportunity in the interplay between patent, copyright, and other intellectual property laws and the Takings Clause. If future litigants and adjudicators appreciate the full potency of the Takings Clause with respect to intellectual property, then the growing gaps in IP protection can be closed, providing much needed security for the intellectual assets that are the building blocks of the Twenty-First Century economy.

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