

## HOECHST-ROUSSEL PHARMACEUTICALS, INC. V. LEHMAN

*By Matthew Hinsch*

Included in the rights granted to a patent holder is the right to prevent others from making, using, offering for sale, or selling the patented invention.<sup>1</sup> The claims of a patent determine the property right from which others can be excluded.<sup>2</sup> A patent granted before June 8, 1995 has a term of 17 years from the day it was issued.<sup>3</sup> Since June 8, 1995, when the Uruguay Round Agreement Act went into effect, the term of a patent is 20 years from the day the inventor files a patent application with the Patent and Trademark Office (PTO).<sup>4</sup>

Unlike most other inventions, drugs must be reviewed for safety by a governmental agency (such as the Food and Drug Administration (FDA)) before they can be commercially marketed.<sup>5</sup> Thus, a drug cannot be marketed until several years after the term of its patent begins.<sup>6</sup> As a result, holders of patents for pharmaceutical products effectively receive less than the full term of their patent.

There is some evidence that this effective reduction in drug patent terms reduces the incentive to invest in research for new drug products. For instance, a decline in the pharmaceutical industry was perceived after the 1962 expansion of FDA power to regulate drugs. Between 1958 and

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1. See 35 U.S.C. § 271(a) (1997); Frank M. Gasparo, *Markman v. Westview Instruments, Inc. and Its Procedural Shock Wave: The Markman Hearing*, 5 J. L. & POL'Y 723, 728 n.20 (1997).

2. See *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1369, 37 U.S.P.Q.2d (BNA) 1773, 1777 (1996).

3. See 35 U.S.C. § 154(c)(1).

4. See *id.*

5. See Susan E. Kopp, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution*, 71 J. PAT. OFF. SOC'Y 945, 949-51 (1989).

6. See James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 451 (1986) ("Much of the loss in effective patent life, if lost patent life is defined as the difference between effective patent life and seventeen years, is accounted for by the time during which innovating firms conduct the tests required to gain FDA approval.").

1979 the number of new chemical entities approved by the FDA fell by an estimated 81%.<sup>7</sup> One commentator has argued:

The current three year lag time between the submission of a pioneer drug to the FDA and approval for introduction to the marketplace is simply unjustified. The three years, combined with the average seven to ten years of research expended to produce the drug, is far too great an investment of time and resources to be economically feasible—unless the drug is used in huge quantities. [citations omitted.]<sup>8</sup>

To address this problem, Congress enacted The Drug Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch/Waxman Act.<sup>9</sup> Title II of this Act includes section 156 of the Patent Act, which allows patent holders to restore some of the time lost in regulatory review to their patent term. In allowing for patent term restoration, Congress hoped to provide an increased incentive for drug research and innovation.<sup>10</sup>

To apply for patent term extension, the patent holder or its agent must file an application with the PTO within 60 days after FDA approval.<sup>11</sup> Section 156(a) permits the extension of a patent term if five conditions are met: (1) the term of the patent has not expired; (2) the term of the patent has not previously been extended; (3) an application has been submitted by the owner of the patent or its agent as described in section 156(d); (4) the product has been subject to a regulatory review before its commercial use; and (5) the commercial use is the first commercial use of the product unless the product is made by a new biotechnological procedure. Section 156(b) describes what patent rights are extended upon approval of the patent extension. According to the legislative history, section 156(b) provides that “[w]hen a product patent claiming the approved product is extended, the holder’s rights are limited to any use of the approved product which was approved before the expiration of the extended term of the patent . . . .”<sup>12</sup>

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7. *See id.* at 450. Of course, this drop in FDA approvals could be due to the elimination of drugs that lack therapeutic value. *See id.*

8. Kopp, *supra* note 5, at 971.

9. *See* CHISUM, CHISUM ON PATENTS § 16.04[5] (1997).

10. *See* H.R. REP. NO. 98-857, pt. I, at 15 (1984) (“The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket governmental approval”).

11. *See* 35 U.S.C. § 156(d)(1) (1997).

12. *See* H.R. REP. NO. 98-857, pt. I, at 39 (1984).

Section 156(c) specifies the period of the extension of the patent term. One important component of this section is that the period of the extension is reduced by any time for which it is determined that the applicant for patent extension did not act with due diligence during the period of the regulatory review.<sup>13</sup> The determination of due diligence, as required in the application by section 156(a)(3), is made under section 156(d). Section 156(d) requires that the application include, among other information, "a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities."<sup>14</sup>

## BACKGROUND

In *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*,<sup>15</sup> the Federal Circuit considered how section 156 should be applied when a pharmaceutical patent holder applies for patent term extension based on a regulatory review period that it did not initiate. Hoechst-Roussel's (Hoechst) United States Patent No. 4,631,286 issued in 1986.<sup>16</sup> It claims the drug 1-hydroxy-tacrine and a method of treating patients in need of memory enhancement.<sup>17</sup> In 1993, Warner-Lambert completed an FDA review of tacrine hydrochloride (marketed as COGNEX), and Hoechst sued for infringement of the '286 patent.<sup>18</sup> Hoechst's '286 patent does not claim tacrine hydrochloride.<sup>19</sup> Tacrine hydrochloride, however, metabolizes into 1-hydroxy-tacrine and other compounds when it is ingested.<sup>20</sup> Thus, Hoechst sued under the theory that a patent is infringed by a drug that, upon ingestion, metabolizes into a chemical that is claimed in the patent.<sup>21</sup> In 1994, a court entered a consent judgment in which Warner-Lambert admitted that tacrine hydrochloride infringes the '286 patent.<sup>22</sup>

While in litigation, Hoechst applied for extension of its '286 patent under section 156 of the Patent Act for the period of the Warner-Lambert-

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13. See 35 U.S.C. § 156(c)(1).

14. See *id.* § 156(d)(1)(D).

15. 109 F.3d 756, 42 U.S.P.Q.2d (BNA) 1220 (Fed. Cir. 1997).

16. See *id.* at 757, 42 U.S.P.Q.2d at 1221.

17. See *id.*

18. See *id.*

19. See *id.*

20. See 109 F.3d at 757, 42 U.S.P.Q.2d. at 1221-22.

21. See *id.*; see also *Zenith Lab., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 30 U.S.P.Q.2d (BNA) 1285 (Fed. Cir. 1994) (finding that infringement may occur if a drug is metabolized *in vivo* into a product claimed by a patent).

22. See *Hoechst*, 109 F.3d at 757, 42 U.S.P.Q.2d at 1222.

initiated FDA review of tacrine hydrochloride.<sup>23</sup> In 1995, the Commissioner of the PTO denied Hoechst's application for patent term extension on two grounds. First, the Commissioner denied Hoechst's application because Hoechst was not involved in the regulatory approval process for tacrine hydrochloride.<sup>24</sup> Second, the application was refused because patent '286 did not claim tacrine hydrochloride.<sup>25</sup>

Hoechst appealed the Commissioner's rejection to the district court and lost.<sup>26</sup> In an unpublished opinion, the district court held that Hoechst was not a proper applicant for patent term extension because the '286 patent did not claim tacrine hydrochloride<sup>27</sup> and because "a patent holder not attempting to market a product was not an intended beneficiary of [section] 156."<sup>28</sup> Hoechst subsequently appealed to the Federal Circuit.

### THE MAJORITY DECISION

A majority of the Federal Circuit three-judge panel, in an opinion by Judge Clevenger, affirmed the district court's decision. The majority held that section 156(a) of the Patent Act requires a patent to claim a product that has been subject to regulatory approval in order to receive patent term extension. Section 156(a) states that "[t]he term of a patent which *claims a product* ... shall be extended if ... (4) the product has been subject to a regulatory review period before its commercial use or sale" (emphasis added). Therefore, the majority found that because Hoechst's '286 patent did not *claim* tacrine hydrochloride (the compound that was reviewed by the FDA), the '286 patent should not be extended.<sup>29</sup>

The majority rejected Hoechst's argument that the legislative history of section 156 of the Patent Act supported a broader interpretation of "claims" to include any product that infringes the claims of a patent. Hoechst cited two sections in the legislative history that addressed how Congress intended "claims" to be interpreted. First, the legislative history states that "[t]he term 'claims' was selected because it is the term used in the patent law to describe the invention which the patent owner or its assignee may prevent others from making, using or selling during the sev-

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23. *See id.*

24. *See id.*

25. *See id.* at 758, 42 U.S.P.Q.2d at 1222.

26. *See id.*

27. *See id.*

28. *Id.* at 758, 42 U.S.P.Q.2d at 1225.

29. *See id.* at 761, 42 U.S.P.Q.2d at 1224-25.

enteen year term of the patent ...."<sup>30</sup> Second, the legislative history states that "[t]he policy which the Committee seeks to implement ... is ... that the first patent ... which claims the approved product, in the sense that the approved product would infringe a claim of that patent ... is the patent which should be rewarded with the extension."<sup>31</sup> In rejecting this argument, the majority cited *Glaxo Operations UK, Ltd. v. Quigg*,<sup>32</sup> and stated that the plain meaning of section 156 should be overridden only if there was an "extraordinary showing of contrary intentions."<sup>33</sup>

### JUDGE NEWMAN'S CONCURRING OPINION

Judge Newman found the legislative history persuasive and thus disagreed with the majority. She noted that the purpose of section 156 was to extend the time during which a patent can be enforced against infringers and found that the majority's plain reading of the section 156(a) was contrary to this purpose. She concluded that "[t]he word 'claim' is used in the statute for ... implementing this purpose, not to provide a loophole when the claim would be directly infringed only upon use of the FDA-approved product."<sup>34</sup>

According to Judge Newman, the district court was wrong when it held that "Hoechst-Roussel, not having itself sought regulatory market approval, could not apply for extension of the term of the '286 patent."<sup>35</sup> Judge Newman argued that, for instance, a licensee, and not the patent holder, could seek regulatory approval under section 156. Citing section 156(a)(3), she noted that an application can be submitted by the patent holder or its agent.<sup>36</sup> Therefore, according to Judge Newman, the statute provides for the scenario where the patent holder and marketing applicant are different, and therefore the district court was wrong when it held that a patent holder could not apply for patent extension if the patent holder had not sought regulatory market approval.

Furthermore, Judge Newman disagreed with the district court's assertion that the applicant for regulatory market approval must have been the

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30. *Id.* at 760, 42 U.S.P.Q.2d at 1224 (citing H.R. REP. NO. 98-857, pt. I, at 37 (1984)).

31. *Id.*

32. 706 F. Supp. 1224, 1227-28, 10 U.S.P.Q.2d (BNA) 1100, 1103 (E.D. Va. 1989), *aff'd*, 894 F.2d 392, 13 U.S.P.Q.2d (BNA) 1628 (Fed. Cir. 1990).

33. *See Hoechst*, 109 F.3d at 758, 42 U.S.P.Q.2d at 1223 (emphasis in original).

34. *Id.* at 764, 42 U.S.P.Q.2d at 1227 (Newman, J., concurring).

35. *Id.* at 761, 42 U.S.P.Q.2d at 1225 (Newman, J., concurring).

36. *See id.* (Newman, J., concurring).

patentee or its agent at the time the approval was sought.<sup>37</sup> Throughout section 156, the statute refers to a variety of contexts where an agent can act in the patent holder's absence. For instance, section 156(d)(1)(D) provides that the applicant or the marketing entity (i.e. the applicant for FDA approval) may contribute evidence of due diligence during the regulatory review period.<sup>38</sup> Thus an independent entity can apply for a regulatory market review and later become the patent holder's agent for patent term extension.

Nevertheless, Judge Newman argued that Hoechst's '286 patent was still not eligible for the patent term extension because section 156 requires that the market applicant participate in the application for patent term extension.<sup>39</sup> For instance, "section 156(d)(1)(D) requires that the applicant for extension provide a description of its activities during the regulatory review period and the dates of such activities; this description may be provided by the marketing entity when the patentee has not itself engaged in such activities."<sup>40</sup> According to Judge Newman, "it is the holder of market approval that is the primary intended beneficiary of section 156."<sup>41</sup> Therefore, since Hoechst was not the marketing applicant and Warner-Lambert (who was the market applicant) did not participate in Hoechst's application, Hoechst could not successfully apply for patent term extension. Finally, Judge Newman rejected Hoechst's argument that 21 C.F.R. § 60.36(b), which states that "the actions of the marketing applicant shall be imputed to the applicant for patent term restoration," removes the need for participation of the marketing applicant.<sup>42</sup> In sum, Judge Newman concurred in result only, finding both bases of the district court's judgment, as well as the majority's reasoning, incorrect.

## DISCUSSION

Faced with a choice between the plain meaning of the statute and strong indications from the legislative history for a different reading of the statute, the Federal Circuit chose the plain meaning of the statute. This decision undercuts the policy goals of the Hatch/Waxman Act and is not consistent with the statutory scheme of the patent system. To meet these policy goals, Congress now must change the language of section 156(a) so

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37. *See id.* (Newman, J., concurring).

38. *See id.* at 762, 42 U.S.P.Q.2d at 1225 (Newman, J., concurring).

39. *See id.* at 763, 42 U.S.P.Q.2d at 1226 (Newman, J., concurring).

40. *Id.* at 762, 42 U.S.P.Q.2d at 1225 (Newman, J., concurring).

41. *Id.* at 761, 42 U.S.P.Q.2d at 1225 (Newman, J., concurring).

42. *See id.* at 762, 42 U.S.P.Q.2d at 1226 (Newman, J., concurring).

that a patent may be extended for the regulatory review period of a product that infringes, but is not claimed by, the patent.

The Hatch/Waxman Act resulted from a Congressional compromise between the competing interests of the generic drug industry and research-based, patent-holding, pharmaceutical companies.<sup>43</sup> Title I and part of Title II of the Hatch/Waxman Act provided generic drug companies with an abbreviated generic drug approval process<sup>44</sup> and overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co* by introducing section 271(e) of the Patent Act.<sup>45</sup> Section 271(e)(1) states that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell ... a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs ....”<sup>46</sup>

The remainder of Title II of the Hatch/Waxman Act, on the other hand, was enacted to promote the interests of pharmaceutical companies that fund research for new drug development. These companies wanted the patent term of their drugs extended to restore the time that they could have marketed their drug but for the FDA regulatory review.<sup>47</sup> In effect, innovative pharmaceutical companies were not receiving the full benefit of the seventeen year patent term because they were not allowed to market their drugs until after a lengthy FDA review. To correct this discrepancy and thus to “create a new incentive for increased expenditures for research and development of ... products which are subject to premarket government approval,”<sup>48</sup> Congress enacted section 156 of the Patent Act to restore some of the patent term lost under government regulatory review. “The incentive is the restoration of some of the time lost on patent life while the product is awaiting pre-market approval.”<sup>49</sup> In sum, the statute was enacted to encourage pharmaceutical companies to fund more research in drug development.<sup>50</sup>

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43. See Kopp, *supra* note 5, at 946.

44. *Id.* at 955-60.

45. See *Hoechst*, 109 F.3d at 763, 42 U.S.P.Q.2d at 1226.

46. 35 U.S.C. § 271 (1997).

47. See Wheaton, *supra* note 6, at 451.

48. See H.R. REP. NO. 98-857, pt. I, at 15 (1984).

49. *Id.*

50. It is unclear what the actual effect of the Hatch/Waxman Act has been on the pharmaceutical industry. At least one commentator has argued that the conditions for patent term extension are too restrictive and that the rights granted are too vague for section 156 to be effective. See Kopp, *supra* note 5, at 968-69. This is supported by the finding that patent holders for approximately one third of new chemical entities approved by the FDA did not even bother to file for patent term extension. See Susan Kucukarslan

The majority in *Hoechst* had two choices with regard to section 156(a): it could uphold the plain meaning of the statute or it could have interpreted the statutory language to encompass the legislative intent that is enunciated in the legislative history. The court stated that an "extraordinary showing of contrary intentions" was necessary to interpret section 156(a) by anything but its plain meaning.<sup>51</sup> The court held that Hoechst's argument did not meet that high standard.<sup>52</sup> Although the court applied the correct standard, they arrived at the wrong result.

Courts have applied the "extraordinary showing" standard for many years.<sup>53</sup> In *Hoechst*, the court cited *Rubin v. U.S.*<sup>54</sup> and *Glaxo* for the "extraordinary showing" standard.<sup>55</sup> Neither case, however, sheds much light on application of the "extraordinary showing" standard. In *Rubin*, the Supreme Court addressed the question of whether pledging stock as collateral for a bank loan constituted an "offer or sale" as recited in the Securities Act of 1933.<sup>56</sup> The Court found that when the terms of the statute were unambiguous, "judicial inquiry is complete, except 'in 'rare and exceptional circumstances.'"<sup>57</sup> The petitioner, however, did not cite any legislative history indicating that Congress intended anything but the plain meaning of the statute.<sup>58</sup> The Court concluded that the legislative history and purposes of the Securities Act of 1933 were consistent with the plain meaning of the statute.<sup>59</sup> Therefore, the statute's plain meaning was upheld.<sup>60</sup>

In *Glaxo*, the Federal Circuit decided whether a drug was the first drug product to be marketed under a patent, as required by section 156(a)(5) of

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& Jacqueline Cole, *Patent Extension Under The Drug Price Competition And Patent Term Restoration Act Of 1984*, 49 FOOD & DRUG L.J. 511, 522 (1994). Others, however, have noted that pharmaceutical company research expenditures have increased since the passage of the Act. See Ralph A. Lewis, *The Emerging Effects Of The Drug Price Competition And Patent Term Restoration Act Of 1984*, 8 J. CONTEMP. HEALTH L. & POL'Y 361, 376 (1992).

51. See *Hoechst-Roussel Pharm., Inc. v. Lehman*, 109 F.3d 756, 760, 42 U.S.P.Q.2d (BNA) 1220, 1223 (Fed. Cir. 1997).

52. See 109 F.3d at 760, 42 U.S.P.Q.2d at 1224.

53. See, e.g., *Crooks v. Harrelson*, 282 U.S. 55, 60 (1930).

54. 449 U.S. 424 (1981).

55. See *Hoechst*, 109 F.3d at 760, 42 U.S.P.Q.2d at 1223.

56. See *Rubin*, 449 U.S. at 427-28.

57. *Id.* at 430.

58. See *id.*

59. See *id.* at 431.

60. See *id.*

the Patent Act for patent term extension.<sup>61</sup> In attempting to deny patent term extension to the applicant, the Commissioner of the PTO argued for a statutory interpretation of section 156(f)(2) that was counter to the plain meaning of the statute.<sup>62</sup> The Federal Circuit stated that the legislative history should be considered, “but only to determine whether a clear intent contrary to the plain meaning exists.”<sup>63</sup> The court found that the legislative history did not provide an explanation of the language in question, but only provided a general policy for the entire Hatch/Waxman Act.<sup>64</sup> Thus, the court in *Glaxo* held that an extraordinary showing had not been made.<sup>65</sup>

The Supreme Court case of *Garcia v. United States*<sup>66</sup> gives somewhat clearer guidance on how to apply the “extraordinary showing” standard. The Court discussed the role of legislative history in applying the “extraordinary showing” standard by stating: “In surveying legislative history we have repeatedly stated that the authoritative source for finding the Legislature’s intent lies in the Committee Reports on the bill, which ‘represent[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.’”<sup>67</sup> As in *Rubin* and *Glaxo*, however, there was no legislative history that addressed the statutory language at issue.<sup>68</sup> Therefore, in *Garcia*, the plain meaning of the statute was applied.<sup>69</sup>

In contrast to the facts in *Garcia*, the Committee Report for section 156(a) addresses the exact controversy at issue in *Hoechst*, and indicates a *clear intent* for how that controversy should be resolved. The legislative history confirms that the authors of the statute intended that patent extension be conferred in the situation where “the approved product would *infringe* a claim of that patent.”<sup>70</sup> This language is crystal clear. Certainly, this quotation from the legislative history is a clear intent by the legislature of a meaning contrary to the plain meaning of the statute, as required by *Glaxo*, *Rubin*, and *Garcia*.

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61. See *Glaxo Operations UK, Ltd. v. Quigg*, 894 F.2d 392, 394, 10 U.S.P.Q.2d (BNA) 1628, 1629 (Fed. Cir. 1990).

62. See *id.*

63. See *id.* at 395, 10 U.S.P.Q.2d at 1630-31.

64. See *id.* at 396, 10 U.S.P.Q.2d at 1631.

65. See *id.* at 399-400, 10 U.S.P.Q.2d at 1633-34.

66. 69 U.S. 70 (1984).

67. *Id.* at 76 (quoting *Zuber v. Allen*, 396 U.S. 168, 186 (1969)).

68. See *Garcia*, 69 U.S. at 77.

69. See *id.*

70. See H.R. REP. NO. 98-857, pt. I, at 38 (1984) (emphasis added).

It is not clear why the majority does not state that it is adopting a textualist or other kind of approach that ignores the legislative history when interpreting statutory language.<sup>71</sup> The fact that the majority states that it will apply a standard that looks to the legislative history and then proceeds to review that history suggests that the court believes that the legislative history should play some role in statutory interpretation. It is wrong for the court to "examine the legislative history to ensure that there exists no clearly expressed legislative intention contrary to the statutory language"<sup>72</sup> and then ignore that the legislative history clearly differs with the plain meaning of section 156(a).

The majority's opinion appears even weaker when considered in the context of the function of the patent system. As Judge Newman notes in her concurring opinion, infringement is "the core of the patent system."<sup>73</sup> Certainly the patent system allows patent holders to prevent others from using techniques that are not even claimed in their patents (e.g., the doctrine of equivalents protects against activities that are similar to, but not the same as, what is claimed).<sup>74</sup> The patent system encourages innovation by allowing inventors protection from *infringement* of their patent claims. The Federal Circuit's ruling in *Hoechst* undercuts these policy goals. Now, under the ruling of *Hoechst*, a FDA-reviewed product that directly infringes the patent does not necessarily allow for patent term extension.<sup>75</sup> The patent is extended only if the invention is within the claims of the patent. Thus, "[t]he distinction drawn by the panel majority leads to the curious result that the '286 claims would be infringed for all purposes of Title

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71. For instance, several courts have held that the legislative history should not be considered when interpreting statutes. See *United States v. Great N. Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written"); *Immigration and Naturalization Serv. v. Cardoza-Fonseca*, 480 U.S. 421, 452 (1987) (Scalia, J., concurring) (arguing against reviewing the legislative history when the statutory language is clear); *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829, 12 U.S.P.Q.2d (BNA) 1644, 1646 (Fed. Cir. 1989) ("Even if the [legislative] history were contrary to the statutory language employed and passed, we would be bound by what the law says, not by what it 'should' have said"). For some of the reasons that commentators have suggested for ignoring legislative history, see W. David Slawson, *Legislative History And The Need To Bring Statutory Interpretation Under The Rule Of Law*, 44 STAN. L. REV. 383 (1992) and David A. Strauss, *Why Plain Meaning*, 72 NOTRE DAME L. REV. 1565 (1997).

72. *Hoechst-Roussel Pharm., Inc. v. Lehman*, 109 F.3d 756, 760, 42 U.S.P.Q.2d (BNA) 1220, 1223 (Fed. Cir. 1997).

73. *Id.* at 764, 42 U.S.P.Q.2d at 1227 (Newman, J., concurring).

74. See *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, \_\_\_ U.S. \_\_\_, 117 S. Ct. 1040, 41 U.S.P.Q.2d (BNA) 1865 (1997).

75. *Hoechst*, 109 F.3d at 764, 42 U.S.P.Q.2d at 1227.

35 except for [section] 156.”<sup>76</sup> As a result, pharmaceutical innovators will not receive the additional benefit that Congress intended to provide them by enacting the Hatch/Waxman Act. Unfortunately, in order to prevent an undeserving applicant from receiving patent term extension, the majority wrongly created a precedent that prevents patent term extension for regulatory reviews of products that infringe, but are not claimed by, a patent.

Judge Newman’s concurring opinion provides a better approach for applying section 156. This approach allows patent term extension for the regulatory review period of any product that infringes the patent. It also prevents patent holders from extending the term of their patents based on regulatory review periods that neither they nor their agents initiated. Thus, pharmaceutical innovators could receive the full incentive of patent term extension that the legislative history supports. Furthermore, by allowing patent term extension only in situations where the regulatory review applicant participates in the extension application process, patent holders such as Hoechst would not receive patent term extensions. Thus Hoechst, which did not lose any of its own time going through FDA review, would not benefit by receiving patent term extension. This would be a fair result.

On the other hand, an agent that licensed the same product from Hoechst and lost time by going through a regulatory review could recoup that time and maintain its license by receiving an extension. In this case, the licensee that lost time in the review process would reap the benefit of additional time to enjoy the advantages of its license. The patent term extension would reward those who went through the review process, thus creating an incentive to continue to produce and commercialize more innovative drug technologies. Judge Newman’s approach would fulfill the legislature’s policy goals that were instituted when Congress passed the Hatch/Waxman Act. The majority’s holding in *Hoechst*, on the other hand, undercuts these goals.

## CONCLUSION

The court should have denied Hoechst’s application for patent term extension because the market applicant did not participate in the application for patent term extension. Unfortunately, the court in *Hoechst* came to the correct decision, but for the wrong reasons. Those wrong reasons are now precedent and undermine the Hatch/Waxman Act’s public policy goals of rewarding pharmaceutical innovators. It remains to be seen to

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76. *Id.*

what extent this ruling will undermine Congress's goal of producing additional incentives to drug innovators.