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# Bayer AG v. Housey Pharmaceuticals: Protection for Biotechnological Research Tools under Section 271(g) Found Wanting

## **Abstract**

[Excerpt] "Research tools, a subset of biotechnological inventions protected by process patents, are "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." Many companies base their business models on the ability to find pharmaceutical products using their proprietary drug discovery research tools. Research tools used for drug discovery 'include bioinformatic methods for identifying the interaction of certain proteins and their association with disease, methods for confirming protein targets, screening assays to identify molecules active against a target, and safety profiling assays."

## **Keywords**

patent, genetic cloning, research tool patents, PCR

## *Bayer AG v. Housey Pharmaceuticals: Protection for Biotechnological Research Tools under Section 271(g) Found Wanting*

MATTHEW BARTHALOW\*

### I. INTRODUCTION

Research tools, a subset of biotechnological inventions protected by process patents, are “tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.”<sup>1</sup> Many companies base their business models on the ability to find pharmaceutical products using their proprietary drug discovery research tools.<sup>2</sup> Research tools used for drug discovery “include bioinformatic methods for identifying the interaction of certain proteins and their association with disease, methods for confirming protein targets, screening assays to identify molecules active against a target, and safety profiling assays.”<sup>3</sup>

Congress enacted the Process Patent Amendments Act of 1988 (“PPAA”) as part of the Omnibus Trade and Competitiveness Act of 1988.<sup>4</sup> Congress enacted 35 U.S.C. § 271(g)<sup>5</sup> of the PPAA to broaden

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1. 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999).

2. Nicholas Groombridge & Sheryl Calabro, *Integra Lifesciences v. Merck – Good for Research or Just Good for Research Tool Patent Owners?*, 22 *Biotechnology L. Rep.* 462, 462 (2003).

3. M. Patricia Thayer & Michelle M. Umberger, *Enforcing U.S. Method Patents: How Much Protection Does 35 U.S.C. Section 271(g) Really Provide*, 4 *Sedona Conf. J.* 85, 86 (2003).

4. Pub. L. No. 100-418, 102 Stat. 1107, 1107 (1988).

5. (g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

process patent protection by providing a remedy for a United States patentee where the patented process was used abroad and the product made by the patented process was subsequently imported, offered for sale, sold, or used in the United States.<sup>6</sup>

Congress addressed the application of the PPAA to biotechnology process patents.<sup>7</sup> Specifically, the legislative history of the PPAA addressed the likely possibility that a foreign manufacturer would use a patented process to clone a gene into a plasmid and deliver the plasmid to a bacterial host.<sup>8</sup> As a result, Congress determined that infringement would occur when the protein product encoded by the gene is imported, offered for sale, sold, or used in the United States without authorization by the United States patentee.<sup>9</sup>

This legislative history aided the Court of Appeals for the Federal Circuit (“Federal Circuit”) in *Bio-Technology General Corp. v. Genentech, Inc.*,<sup>10</sup> the only Federal Circuit case to interpret “made by” under section 271(g).<sup>11</sup> In *Bio-Technology*, the Federal Circuit found that “[t]he legislative history precisely anticipated this fact situation and indicated Congress’s intent that infringement of a process for making a plasmid is not to be avoided by using it to express its intended protein.”<sup>12</sup>

Unfortunately, the legislative history does not directly address whether a drug candidate is a “product” under section 271(g) when a patented research tool is used to identify the drug candidate.<sup>13</sup> Thus, Congress did not anticipate the fact pattern developed in *Bayer AG v. Housey Pharmaceuticals*,<sup>14</sup> which required the Federal Circuit to interpret section 271(g) in relation to the use of a patented research tool abroad.<sup>15</sup> The Federal Circuit held that the word “product” refers to a “physical good” and “made” is synonymous with “manufactured.”<sup>16</sup> More specifically, the court held “that in order for a product to have been ‘made by a process patented in the United States[,]’ the product must be a physical article that was ‘manufac-

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(2) it becomes a trivial and nonessential component of another product.

35 U.S.C. §271(g) (2000).

6. Sen. Rpt. 100-83 at 2 (June 23, 1987).

7. *Id.* at 30.

8. *Id.* at 49.

9. *Id.*

10. 80 F.3d 1553 (Fed. Cir. 1996).

11. *Id.* at 1561.

12. *Id.*

13. *See* Sen. Rpt. 100-83 at 49.

14. 340 F.3d 1367 (Fed Cir. 2003).

15. *See id.*

16. *Id.* at 1372.

ured.”<sup>17</sup> Therefore, the production of information is not a “product” under section 271(g).<sup>18</sup> Additionally, “the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured.”<sup>19</sup>

This article argues that section 271(g) should be broadened to encompass as an infringing act the use of a drug candidate in the United States when discovered by a patented research tool used abroad. Specifically, this article proposes that the courts should interpret the word “product” to cover the discovery of the drug as embodied by the actual drug. The phrase “made by” should extend to *all* steps taken to bring a drug to market rather than be limited to physical “manufacturing.”

This article will discuss the PPAA and the *Bio-Technology* case as background to the *Bayer* decision,<sup>20</sup> and will further explore the reasoning adopted by the Federal Circuit in *Bayer*.<sup>21</sup> As part of a critical analysis of the Federal Circuit’s reasoning in *Bayer*, this article will argue that section 287 cannot be used to limit the scope of section 271(g) because Congress enacted section 287(b) only to address the concerns of importers of goods manufactured abroad.<sup>22</sup> Additionally, the exceptions in section 271(g) should not be limited to “manufactured” physical goods because the exceptions were purposefully crafted to be narrow.<sup>23</sup> Moreover, section 271(g) was intended to broaden International Trade Commission (“ITC”) protection.<sup>24</sup> Congress enacted section 271(g) to provide remedies to parties that could not seek relief through the ITC and to provide the patent-type infringement analysis the federal courts were in the best position to provide.<sup>25</sup> Further, Congress intended section 271(g) to apply to the commercial use of biotechnological patented process abroad even if the product of the use will not be manufactured by the process directly.<sup>26</sup> Still further, *Bayer* is analogous to *Bio-Technology* because the discovery of an important biological property of a drug candidate is the product and is embodied in the drug itself.<sup>27</sup> Finally, this article will show how sound economic policy encourages this interpretation.<sup>28</sup>

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17. *Id.* at 1377.

18. *Id.*

19. *Id.*

20. *Infra* pts. II(B)-(C).

21. *Infra* pt. III.

22. *Infra* pt. IV(B).

23. *Infra* pt. IV(C).

24. *Infra* pt. IV(D).

25. *Id.*

26. *Infra* pt. IV(E).

27. *Infra* pt. IV(F).

28. *Infra* pt. V.

The Federal Circuit strongly supported domestic protection of biotechnology research tool patents in the recent *Integra Lifesciences v. Merck* decision.<sup>29</sup> The protection afforded in *Integra* cannot be reconciled with the lack of protection in *Bayer* because strong domestic protection of research tools is incompatible with a lack of foreign protection.<sup>30</sup> As it now stands, companies will be encouraged to perform pre-clinical research abroad.<sup>31</sup>

## II. BACKGROUND

### A. Patented Research Tools and Enforcement Thereof

Scientists performing biotechnology related research use research tools everyday. The National Institutes of Health has defined research tools as “tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.”<sup>32</sup> This article limits research tools to tools used in the development of new biotechnological or pharmaceutical products where the products do not themselves physically incorporate the research tool.<sup>33</sup>

Although it is argued that the “stacking”<sup>34</sup> of research tool patents are creating transaction costs that effectively prevent scientists from using these tools, research tools continue to receive patent protection in the United States.<sup>35</sup> In the past, the perceived transaction costs associated with “stacking” has led many to believe that the courts were adverse to research tool patentees.<sup>36</sup>

Further, there are challenges associated with the domestic enforcement of research tool patents.<sup>37</sup> These challenges include: (1) patent misuse as a common defense to an infringement claim when the research tool patent is asserted against the end product; (2) validity attacks on the patent for lack-

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29. 2003 U.S. App. LEXIS 27796 (opinion previously reported at 331 F.3d 860 (Fed. Cir. 2003)); *infra* pt. V(A).

30. *Infra* pt. V(B).

31. *Id.*

32. 64 Fed. Reg. at 72,092 n.1.

33. See Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 14 (2001).

34. “Stacking” is the need for multiple patents from different owners in order to carry out research.

35. Mueller, *supra* n. 33, at 7-8.

36. See generally Groombridge, *supra* n. 2, at 462.

37. See Steven J. Hultquist, *Reach-Through Royalties: The Scope of Research Tool Patents*, 86 J. Pat. & Trademark Off. Socy. 285, 286 (2004).

ing a written description of the end product; (3) that damages cannot be imposed when the product of the patented process is only knowledge or information; and (4) problems associated with determining a reasonable royalty.<sup>38</sup>

Notwithstanding arguments against and challenges associated with domestic enforcement, many biotechnological and pharmaceutical companies have invested heavily in the patenting of research tools.<sup>39</sup> Many companies base their business models on the ability to find biotechnological or pharmaceutical products using their proprietary drug discovery tools.<sup>40</sup> Tools used for drug discovery “include bioinformatic methods for identifying the interaction of certain proteins and their association with disease, methods for confirming protein targets, screening assays to identify molecules active against a target, and safety profiling assays.”<sup>41</sup>

Other companies have effectively circumvented United States patent protection for research tools.<sup>42</sup> In the industry it “is no secret that more than a few biotech and pharmaceutical companies perform drug discovery offshore and then import the results” to circumvent domestic protection.<sup>43</sup> As a result, offshore drug discovery creates tension between companies owning research tool patents and those companies who seek to use the research tools to perform drug discovery.<sup>44</sup>

### B. *The Process Patent Amendments Act of 1988*

The PPAA broadened process patent protection to encompass many foreign acts that had previously been used to circumvent United States patent protection.<sup>45</sup> The legislative history of the PPAA directly states the “importance of protecting ‘new manufacturing techniques’ and emphasizes the need to prohibit the importation of any ‘product,’ ‘substance,’ ‘good,’ and ‘tangible item’ made by patented processes.”<sup>46</sup> One articulation of the purpose of the PPAA was to grant patentees a “right to sue for damages and seek an injunction in a federal district court when someone, without authorization, uses or sells in the United States, or imports into the United

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38. A per-use royalty basis may be grossly disproportionate to the end value realized by the user of the research tool, while reach through royalties based on the value of the end product faces the same challenges as described for enforcement of process patents generally. *Id.* at 286.

39. Thayer, *supra* n. 3, at 86.

40. Groombridge, *supra* n. 2, at 462.

41. Thayer, *supra* n. 3, at 86.

42. See Donald J. Featherstone & Jorge A. Goldstein, *Federal Circuit Holds that Importing Data is Not Patent Infringement*, 10 No. 2 *Intell. Prop. Strategist* 1, 1 (2003).

43. *Id.*

44. Groombridge, *supra* n. 2, at 462.

45. See Sen. Rpt. 100-83 at 29-31.

46. Thayer, *supra* n. 3, at 88.

States a product made by their patented process.”<sup>47</sup> Additionally, Congress enacted the PPAA as a response to *Deepsouth Packing v. Laitram*, “which held that the intentional exportation of components [from the U.S.] to be combined into a patented article was not an act of infringement.”<sup>48</sup> Congress sought to prohibit this act through the PPAA.<sup>49</sup>

### C. *Bio-Technology v. Genentech: Anticipated by Congress*

In *Bio-Technology*, the only Federal Circuit decision to interpret “made by” under section 271(g), the Federal Circuit found that the legislative history of the PPAA anticipated the facts.<sup>50</sup> Genentech was the assignee of two patents directed to a method for producing human growth hormone (“hGH”).<sup>51</sup> The first patent provides a method for directly expressing hGH in a bacterial host by using “a recombinant DNA method for producing a 191- or 192- amino acid human growth hormone product that is identical, or essentially identical, and functionally equivalent to the natural hormone.”<sup>52</sup> The method provides for modification of the hGH cDNA<sup>53</sup> by removing the leader sequence and replacing the leader sequence with a bacterial leader sequence.<sup>54</sup> The modified hGH cDNA is *directly* inserted into bacterial cells for expression of the hGH protein.<sup>55</sup> The second patent is for essentially the same process, except that the modified cDNA is first inserted into a plasmid,<sup>56</sup> and then the plasmid is transferred into the bacterial host.<sup>57</sup> The bacterium expresses the hGH protein encoded by the hGH gene located on the plasmid.<sup>58</sup>

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47. Sen. Rpt. 100-83 at 29.

48. *Bayer*, 340 F.3d at 1374.

49. *Id.*

50. 80 F.3d at 1561.

51. *Id.* at 1556.

52. *Id.*

53. While a human gene encoded by DNA has sequences that are both translated into the amino acids that form a protein and sequences that are not translated, cDNA contains only the sequences that are translated into the amino acid sequence that make the final protein product. Biotechterms, <http://biotechterms.org/sourcebook/savelinktermquery.php3?COMPLEMENTARY%DNA%cDNA> (accessed November 17, 2005).

54. *Bio-Technology*, 80 F.3d at 1557.

55. By “*directly* inserted,” the method provides that the cDNA will splice (placed within) a particular site on a bacterial chromosome where the bacteria cell will express the hGH protein of the modified hGH gene. *Id.*

56. A “plasmid” is a piece of DNA separate from bacterial chromosomes that is capable of being inserted into the bacteria and the genes on the plasmid are expressed by the same mechanism that expresses genes on a bacterial chromosome. Biotechterms, <http://biotechterms.org/sourcebook/saveidretrieve.php3?id=1486> (accessed November 17, 2005).

57. *Bio-Technology*, 80 F.3d at 1557.

58. *Id.*



In district court, Genentech counter-claimed against Bio-Technology General (“BTG”) and moved for a preliminary injunction. Genentech argued that importation by BTG of hGH from Israel would literally infringe under section 271(g). The district court granted the motion for a preliminary injunction.<sup>59</sup>

In the Federal Circuit, the issue in *Bio-Technology* was whether hGH was a product of the patented process.<sup>60</sup> Because “the plasmid product of the claimed process and hGH are entirely different materials, one being more than materially changed in relation to the other,” BTG argued that hGH was not “made by” the process.<sup>61</sup> The Federal Circuit found, however, that “[t]he legislative history precisely anticipated this fact situation and indicated Congress’s intent that infringement of a process for making a plasmid is not to be avoided by using it to express its intended protein.”<sup>62</sup> Therefore, the Federal Circuit held that there was no error in the district court’s determination that hGH is “made by” the patented process.<sup>63</sup>

The holding in *Bio-Technology* is narrow and only holds that a protein is a product that is “made by” a process directed to genetically engineer a bacterium to produce the desired protein. As will be discussed below, the holding in *Bayer* is also narrow and only interprets “made by” in relation to a patented research tool used abroad. Nevertheless, the *Bayer* decision has consequences that affect the whole biotechnological and pharmaceutical industry.

### III. STATEMENT OF THE CASE: *BAYER AG V. HOUSEY PHARMACEUTICALS*

#### A. Background

Housey was the assignee of three United States patents all entitled “Method of Screening for Protein Inhibitors and Activators.”<sup>64</sup> The patents are directed to a method where a cell line engineered to over express a particular protein is compared to the original non-engineered cell line.<sup>65</sup> By applying substances (e.g. drug candidates) to both cell lines, the method determines whether that substance is an inhibitor or activator of the protein of interest.<sup>66</sup> Therefore, “if a link between a protein and a disease is dis-

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59. *Id.*

60. *Id.* at 1560.

61. *Id.* at 1561.

62. *Id.*

63. *Id.*

64. *Bayer*, 340 F.3d at 1368-69.

65. *Id.* at 1369.

66. *Id.*

covered, the disclosed method provides a process for identifying the effect that different agents [e.g. drug candidates] have on the activity of the suspect protein.”<sup>67</sup> In other words, an established link between a protein and a disease allows the method to identify potential drug candidates.<sup>68</sup>

On March 6, 2001, Bayer brought suit in United States District Court for the District of Delaware, seeking a declaratory judgment that the patents were invalid, unenforceable, and not infringed by Bayer.<sup>69</sup> Housey counter-claimed that Bayer directly contributed to the infringement of the patents under section 271(g).<sup>70</sup> Housey asserted pursuant to 35 U.S.C. § 295 that there was a substantial likelihood that the methods used by Bayer to identify a potential drug candidate infringed patents owned by Housey.<sup>71</sup> Bayer filed a motion to dismiss arguing that section 271(g) “applies only to methods of manufacture,” and does not “cover methods of use.”<sup>72</sup>

The district court found the infringement claim to be twofold. One, infringement based on the sale of a drug identified by the patented method in the United States. Two, infringement based on the importation into or use in the United States of knowledge and information associated with the identification of the drug using the patented method. The district court dismissed the infringement claim because “upon the plain reading of the statute. . . [s]ection 271(g) addresses only products derived from patented manufacturing processes.”<sup>73</sup>

### B. Federal Circuit Analysis

On appeal, the Federal Circuit found that the plain meaning of “made by” was ambiguous. The parties did not dispute that if “made by” meant “manufacture,” then the statute must only refer to “physical goods.” The Federal Circuit found that dictionaries had both narrow and broad definitions of “made” that were and were not limited to “manufacturing.” Because the text of section 271(g) was ambiguous, the court looked to other provisions within the statute for guidance.<sup>74</sup>

The Federal Circuit reasoned that “[b]y referring to the party that produces a product as a ‘manufacturer’ and the maker as a ‘person engaged in the manufacture of a product,’ the statute clearly contemplates that ‘made’ means ‘manufactured.’” The reasoning relied on section 287(b)(3)(B)(iii)

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67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* at 1370.

73. *Id.*

74. *Id.* at 1372.

of the PPAA, where “the Act describes a person that uses a patented process to ‘produce’ a product as a ‘manufacturer.’” Further, the court cited section 287(b)(4)(A) reference to “‘a person then engaged in the manufacture of a product’ as a person that makes the product” for additional support.<sup>75</sup>

Moreover, the Federal Circuit found other reasons to conclude “that the statute is concerned exclusively with products that are physical goods produced by a manufacturing process” based on the exceptions in section 271(g).<sup>76</sup> The court found the statutory exception of section 271(g), which “rules out infringement where the allegedly infringing product ‘is materially changed by a subsequent processes[,]’” difficult to apply to information itself.<sup>77</sup> Similarly, the court had difficulty applying the second component exception to information.<sup>78</sup> The second exception applies when “the accused product ‘becomes a trivial and nonessential component of another product.’”<sup>79</sup> The Federal Circuit found that the second exception “also appears to contemplate a physical product.”<sup>80</sup> Housey argued that Congress would use “manufacture” if it purposely meant to narrow the statute.<sup>81</sup> Nevertheless, the court rejected this argument because “Congress, needless to say, is permitted to use synonyms in a statute.”<sup>82</sup>

The court next turned to the legislative history and found no affirmative attempt by Congress to protect information as a product.<sup>83</sup> The Federal Circuit found that section 271(g) was enacted “to provide new remedies to supplement existing remedies available from the International Trade Commission (“ITC”) under 19 U.S.C. § 1337.”<sup>84</sup> Specifically, section 271(g) “address[es] the same ‘articles’ as were addressed by section 1337, but [adds] additional rights against importers of such ‘articles.’”<sup>85</sup> Nevertheless, the court found nothing in section 1337 suggesting that information was covered.<sup>86</sup>

Although the Federal Circuit found nothing to suggest section 1337 covered information as a product, the court noted that “the legislative history did not affirmatively [intend] to limit coverage to [only] manufactured

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75. *Id.*

76. *Id.*

77. *Id.* at 1372-73.

78. *Id.*

79. *Id.* at 1373.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.* at 1374, n. 9.

84. *Id.* at 1373.

85. *Id.* at 1374.

86. *Id.*

‘articles.’”<sup>87</sup> Citing two Senate Reports, the Federal Circuit explained that the aim of section 271(g) was “to declare it to be patent infringement to import into, or to use or sell in the United States, a product manufactured by a patented process.”<sup>88</sup> The court explained that “the primary target of the United States process patentholder will naturally be the manufacturer, who is practicing the process and importing the resulting goods into the United States.”<sup>89</sup> Additionally, the court cited other congressional reports showing “concern over competition between domestic and foreign manufacturers.”<sup>90</sup>

Despite congressional concern about foreign competition, the Federal Circuit was primarily concerned that “a person possessing the allegedly infringing information could, under Housey’s interpretation, possibly infringe by merely entering the country.”<sup>91</sup> The Federal Circuit concluded that “it is best to leave to Congress the task of expanding the statute if we are wrong in our interpretation.”<sup>92</sup>

### C. Holding

Therefore, the Federal Circuit held “that in order for a product to have been ‘made by a process patented in the United States[,]’ it must have been a physical article that was ‘manufactured’ and that the production of information is not covered.” Next, the court determined “whether a drug that was identified as useful through the use of a patented process is a ‘product which [was] made by [that] process.’” The court stated “it is beyond dispute that a drug is a physical product that has been manufactured.” The court further distinguished the facts in *Bayer* from the facts in *Bio-Technology* noting that “unlike the process in *Bio-Technology*, the patented process is not used in the actual synthesis of the drug product.” The Federal Circuit therefore held that “the process must be used directly in the manufacture of the product, and not merely as a predicate process to identify the product to be manufactured.”<sup>93</sup>

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87. *Id.*

88. *Id.* (quoting Sen. Rpt. 98-663 at 1 (Sept. 24, 1984)).

89. *Id.* at 1375 (quoting Sen. Rpt. 100-83 at 39).

90. *Id.* at 1376.

91. *Id.*

92. *Id.* at 1376-77.

93. *Id.* at 1377.

## IV. CRITICAL ANALYSIS OF FEDERAL CIRCUIT'S REASONING

## A. Introduction

This note argues that section 271(g) should be broadened to encompass as an infringing act the use of a drug candidate in the United States when discovered by a patented research tool used abroad. Specifically, this article proposes that the courts interpret the word “product” to cover the discovery of the drug as embodied by the actual drug. The phrase “made by” should extend to *all* steps taken to bring a drug to market rather than be limited to physical “manufacturing.”

This article agrees with the Federal Circuit in that information *per se* is not a “product” and that “it is beyond dispute that a drug is a physical product” under section 271(g).<sup>94</sup> Further, “made by” is ambiguous according to the plain meaning of the statute and can be interpreted broadly to encompass more than traditional “manufacturing.”<sup>95</sup> Additionally, the Federal Circuit recognized that the legislative history of section 271(g) “did not *affirmatively* suggest an intent to limit coverage to manufactured ‘articles.’”<sup>96</sup>

Section 287 cannot be used to limit the scope of section 271(g).<sup>97</sup> Congress enacted section 287(b) to only address the concerns of importers of goods manufactured abroad.<sup>98</sup> Additionally, the exceptions in section 271(g) should not limit the scope of section 271(g) to “manufactured” physical goods.<sup>99</sup> The exceptions in section 271(g) were purposefully crafted to be narrow.<sup>100</sup> Moreover, section 271(g) was intended to broaden ITC protection. Congress enacted section 271(g) to provide remedies to parties that could not seek relief through the ITC and to provide the patent-type infringement analysis the federal courts were in the best position to provide.<sup>101</sup> Further, Congress intended section 271(g) to apply to the commercial use of biotechnological patented process abroad even if the product of the use will not be manufactured by the process directly.<sup>102</sup> Still further, *Bayer* is analogous to *Bio-Technology* because the discovery of an important biological property of a drug candidate is the product and is embodied

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94. *Supra* n. 93.

95. *Supra* n. 74.

96. *Bayer*, 340 F.3d at 1374 (emphasis added).

97. *Infra* pt. IV(B).

98. *Id.*

99. *Infra* pt. IV(C).

100. *Id.*

101. *Infra* pt. IV(D).

102. *Infra* pt. IV(E).

in the drug itself.<sup>103</sup> Finally, sound economic policy encourages this interpretation.<sup>104</sup> The Federal Circuit strongly supported domestic protection of biotechnology research tool patents in the recent *Integra* decision.<sup>105</sup> The protection afforded in *Integra* cannot be reconciled with the lack of protection in *Bayer*.<sup>106</sup> Strong domestic protection of research tools is incompatible with a lack of foreign protection because companies will be encouraged to perform pre-clinical research abroad.<sup>107</sup>

B. *Section 287(b) is Intended to be Narrower in Scope than Section 271(g)*

The Federal Circuit inference that “made by” under section 271(g) is equivalent to “manufactured” under section 287(b) is not justified. Section 287(b) cannot be used to limit the scope of section 271(g) because section 271(g) was enacted to address the concerns of importers of goods manufacturers abroad. 35 U.S.C. § 287 is entitled *Limitation on damages and other remedies; marking and notice*. Section 287(b) was enacted to provide “limitations on the remedies available to a process patentholder when infringement is based on” section 271(g).<sup>108</sup> Section 287(b)(4)<sup>109</sup> is a pro-

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103. *Infra* pt. IV(F).

104. *Infra* pt. V.

105. 331 F.3d 860; *infra* pt. V(A).

106. *Infra* pt. V(B).

107. *Id.*

108. Sen. Rpt. 100-83 at 52.

109. (4)(A) For purposes of this subsection, a “request for disclosure” means a written request made to a person then engaged in the manufacture of a product to identify all process patents owned by or licensed to that person, as of the time of the request, that the person then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold, offered for sale, or used in, the United States by an unauthorized person. A request for disclosure is further limited to a request--

(i) which is made by a person regularly engaged in the United States in the sale of the same type of products as those manufactured by the person to whom the request is directed, or which includes facts showing that the person making the request plans to engage in the sale of such products in the United States;

(ii) which is made by such person before the person's first importation, use, offer for sale, or sale of units of the product produced by an infringing process and before the person had notice of infringement with respect to the product; and

(iii) which includes a representation by the person making the request that such person will promptly submit the patents identified pursuant to the request to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the person making the request, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

(B) In the case of a request for disclosure received by a person to whom a patent is licensed, that person shall either identify the patent or promptly notify the licensor of the request for disclosure.

(C) A person who has marked, in the manner prescribed by subsection (a), the number of the process patent on all products made by the patented process which have been offered for sale or sold by that person in the United States, or imported by the person into the United States, before a request for disclosure is received is not required to respond to the request for disclosure. For purposes of the preced-

cedure enacted to help non-manufacturing groups likely to violate section 271(g) to obtain the necessary information from the manufacturers they receive goods from to avoid such a violation.<sup>110</sup> The procedure outlined in section 287(b)(4) is “necessary because an importer of a product from a foreign manufacturer is ordinarily unable to obtain specific information from his supplier regarding the process used in manufacturing the imported product.”<sup>111</sup>

The procedure described in section 287(b)(4) addresses the concerns of one limited group affected by the enactment of section 271(g), namely importers. The first step in the procedure outlined in section 287(b)(4) is a formal request by a party “who is engaged in, or intends to be engaged in, the sale of a particular product.” The request is made to parties already engaged in the manufacture of the product and should be made before the requesting party participates in an activity that could constitute infringement under section 271(g). The second step is the patentee’s response to the request which is expected to identify “all process patents owned by or licensed to him that he reasonably believes could be used to make his own product.” Since it was envisioned that the requesting party would be an importing party, the “request for disclosure must include a representation . . . that [the requesting party] will submit the [patentee’s] response to its manufacturer.”<sup>112</sup>

If the procedure is followed, section 287(b)(3) qualifies section 287(b)(4) by deeming the defendant importer to have acted in good faith when determining remedies for infringement, and thus avoiding treble damages.<sup>113</sup> Section 287(b)(3)(B) provides that a defendant importer acts

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ing sentence, the term “all products” does not include products made before the effective date of the Process Patent Amendments Act of 1988.

35 U.S.C. § 287(b)(4) (1999).

110. Sen. Rpt. 100-83 at 53.

111. *Id.*

112. *Id.* at 54.

113. (3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider--

- (i) the good faith demonstrated by the defendant with respect to a request for disclosure,
- (ii) the good faith demonstrated by the plaintiff with respect to a request for disclosure, and
- (iii) the need to restore the exclusive rights secured by the patent.

(B) For purposes of subparagraph (A), the following are evidence of good faith:

- (i) a request for disclosure made by the defendant;
- (ii) a response within a reasonable time by the person receiving the request for disclosure; and
- (iii) the submission of the response by the defendant to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the defendant, together with a request for a written statement that the process claimed in any patent disclosed in the response is not used to produce such product.

The failure to perform any acts described in the preceding sentence is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances include the case in which, due to

in good faith when he submits the plaintiff's response to the request for disclosure to the supplier's manufacturer with a request for a written statement from the manufacturer that the process used in manufacturing does not use any of the plaintiff's disclosed patented processes. Therefore, sections 287(b)(3) cannot be used to limit the scope of section 271(g) because it was enacted to address the concerns of importers of goods manufacturers abroad.

Further, section 287(b) applies a stricter standard of notice than section 287(a)<sup>114</sup> to certain groups of process patent infringers.<sup>115</sup> Section 287(a) existed before the enactment of the PPAA and provided that notice was required for *patented products* in order to recover damages from an infringer.<sup>116</sup> Notice is not required on *unpatented products* made by a *patented process* when performed in the United States.<sup>117</sup> However, this stricter standard does not apply to three categories of infringers, including those who actually used the process.<sup>118</sup> Notably, if Bayer was found to be infringing, the limitation on damages under section 287(b) would not apply to Bayer.

Section 271(g) is broader in scope than section 287(b). Section 287(b) made reference to a manufacturer as a party that produces a product and the maker as a "person engaged in the manufacture of a product"<sup>119</sup> because section 287(b) was enacted to address the situation described above. The purpose of section 271(g) was to broaden process patent protection by providing a remedy for a United States patentee where the patented process was used abroad and the product made by the patented process was subsequently imported, offered for sale, sold, or used in the United States.<sup>120</sup>

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the nature of the product, the number of sources for the product, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

35 U.S.C. § 287(b)(3) (1999).

114. (a) Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

35 U.S.C. § 287(a) (1999).

115. Sen. Rpt. 100-83 at 52.

116. *Id.*

117. *Id.*

118. *Id.*

119. 35 U.S.C. § 287(b)(4)(A) (1999).

120. Sen. Rpt. 100-83 at 2.



Section 287(b) addresses concerns of importers who import a product of a patented process used abroad. On the other hand, section 271(g) also provides a remedy when the product is used or sold in the United States.

### C. *Exceptions Swallow the Intent of the Rule*

Congress crafted the exceptions in section 271(g) narrowly because Congress wanted the courts to determine the scope of section 271(g) without being unnecessarily hampered.<sup>121</sup> The legislative history did not affirmatively address the use of a patented research tool abroad probably because this issue was simply not considered.<sup>122</sup> Further, Congress never affirmatively dealt with information as a product for the same reason.<sup>123</sup> The Federal Circuit's reasoning that information should not be considered a product under section 271(g) is sound. Nevertheless, section 271(g) was not enacted to protect only "products that are physical goods produced by a manufacturing process."<sup>124</sup> The exceptions in section 271(g) were crafted narrowly to prevent the exception of too many products that have been changed in insignificant ways, but left to judicial discretion the determination of the scope of section 271(g) protection.<sup>125</sup> Further, unlike other foreign patent statutes that use the word "directly" to modify "made," Congress decided that the "courts will be in a better position" to settle proximity issues without the "directly" standard "constraining their judgment."<sup>126</sup>

The Federal Circuit was aware that Congress gave the courts the duty to determine the scope of section 271(g).<sup>127</sup> As the Federal Circuit stated in *Bio-Technology*, the exceptions in section 271(g) only answer the question of "what products 'will . . . not be considered' to have been 'made by' a patented process."<sup>128</sup> Section 271(g) "does not specify what products will be considered to have been 'made by' the patented process, apparently because Congress wanted the courts to resolve this critical question of proximity . . . on a case-by-case basis."<sup>129</sup>

Further, Congress established a two-part test to help courts interpret the scope of the exceptions to section 271(g).<sup>130</sup> The two-part test is con-

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121. *See id.* at 49.

122. *See id.* at 52.

123. *See id.*

124. *See Bayer*, 340 F.3d at 1372.

125. Sen. Rpt. 100-83 at 49.

126. *Id.*

127. *Bio-Technology*, 80 F.3d at 1561.

128. *Id.*

129. *Id.*

130. Sen. Rpt. 100-83 at 50.

sistent with a broad interpretation of section 271(g), which makes the offshore use of a patented research tool to identify a drug candidate subsequently used in the United States an infringing act. The first part of the test is not met “if it would not be possible or commercially viable to make that product but for the use of the patented process.”<sup>131</sup> If Housey’s patented research tool was the only way or only commercially viable way to identify the drug candidate, Bayer’s actions would not be excluded under this part of the test. The second part of the test allows an exception under section 271(g) if additionally unpatented steps were taken that physically and materially change the product.<sup>132</sup> The drug candidate is not physically nor materially changed when used in the United States. Further, a material change is one that is related to the physical or chemical property of the product.<sup>133</sup> The use of the research tool by Bayer is actually what identified the material chemical/biological property of the drug candidate. The identification of the chemical/biological property gave the drug candidate value.

#### D. Section 271(g) Broadened Protection Consistent with ITC Protection

Congress enacted section 271(g) to broaden protection consistent with ITC protection because section 271(g) provides remedies to parties that could not seek relief through the ITC.<sup>134</sup> Although Congress enacted section 271(g) to provide additional remedies to process patent owners because “[t]he ITC, unlike a Federal Court in a patent infringement suit, can award no damages,” Congress also enacted section 271(g) to protect parties that could not meet the more elaborate test needed to exclude infringing products by an ITC order.<sup>135</sup> Included in the ITC test is that a patentee “must show that there is an industry in the United States which generally means that the patentholder must practice a patented process commercially.”<sup>136</sup> Congress recognized that this approach conflicts with the policy<sup>137</sup> behind the United States patent system because it offers no protection when the inventor “chooses not to commercialize the invention.”<sup>138</sup> Despite the inconsistency between United States patent policy and the ITC approach, Congress recognized that “the ITC forum will remain a useful

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131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.* at 49.

135. *Id.* at 37.

136. *Id.*

137. A patent grants the right to exclude others, but does not place an affirmative duty on the patentee to practice the invention. *See e.g. Cont'l. Paper Bag v. E. Paper Bag*, 210 U.S. 405, 424 (1908).

138. Sen. Rpt. 100-83 at 37.

supplement” because it “can provide speedy and comprehensive injunctive relief . . . while the patentholder awaits the outcome of the trial in federal court.”<sup>139</sup>

Additionally, Congress wanted the federal courts to provide the patent-type infringement analysis the federal courts are in the best position to provide.<sup>140</sup> Further, the ITC in the past recommended “that a distinction be maintained between the patent-type protection for process inventions . . . and the trade-type protection currently afforded by the ITC” because the expertise of the ITC is in micro-economic analysis.<sup>141</sup> Therefore, in enacting section 271(g), Congress contemplated a broader statutory scheme and thus, did not merely add additional remedies that were not available under the ITC.

Congress enacted section 271(g) to provide remedies to parties that could not seek relief through the ITC and to provide the patent-type infringement analysis the federal courts were in the best position to provide in all cases.<sup>142</sup> This analysis includes determining what physical “articles” would amount to “products” under section 271(g).

A drug candidate identified using a patented research tool is an article consistent with the broader interpretation of articles under the ITC. The language of section 1337 attempts to cover any physical product associated with a patented process used abroad. Even if section 271(g) was enacted to only cover the same articles as 19 U.S.C. § 1337(a)(1)(B),<sup>143</sup> the Federal Circuit concedes that the language of section 1337 is broader on its face than the language of section 271(g).<sup>144</sup> Section 1337 protects articles that “are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.”<sup>145</sup>

ITC protection, as the language indicates, attempts to cover any physical product associated with a patented process used abroad.<sup>146</sup> Section 271(g) was enacted as broad legislation where the existence of the ITC

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139. *Id.* at 38.

140. *Id.*

141. *Id.*

142. *Id.* at 38, 49.

143. (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under Title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B) (2004).

144. *Bayer*, 340 F.3d at 1374 n. 9.

145. 19 U.S.C. § 1337(a)(1)(B)(ii); *see also Bayer*, 340 F.3d at 1374 n. 9.

146. 19 U.S.C. § 1337(a)(1)(B)(ii).

would act as a supplemental forum to quickly procure injunctions.<sup>147</sup> Although the language of section 1337 does not suggest that information is covered, the language does suggest that section 271(g) was intended to cover more than manufactured physical goods.

#### E. Legislative Intent

Congress enacted section 271(g) to deter commercial uses of biotechnology process patents abroad.<sup>148</sup> Congress wanted the courts to determine the scope of “made by” and therefore Congress specifically left to the courts the task to expand section 271(g) interpretation consistent with the goals of section 271(g) enactment.<sup>149</sup> Congress broadly recognized the importance of enacting section 271(g) to protect biotechnology process patents, stating that “[p]rocess patents promise to be increasingly important to a number of industries in the coming years . . . above all in the fields of biotechnology and bioengineering research.”<sup>150</sup> Congress later noted “that many of the ‘products’ produced by patented biotechnology processes are themselves ‘used’ in the manufacture of another product which is introduced into commerce.”<sup>151</sup> Further, Congress stated that the “bill’s provisions limiting remedies against users are not intended to apply to such commercial uses.”<sup>152</sup>

Congress probably intended section 271(g) to apply to commercial uses of biotechnology patented process abroad even if the product of the use will not be manufactured by the process directly. To illustrate this statement, Congress used the example of a process patent for engineering a bacterium that will produce an unpatented end product.<sup>153</sup> This example is cited in *Bio-Technology* as showing Congress’s affirmative attempt to protect the process patents owned by Genentech.<sup>154</sup> This example was the only illustration in the Senate Report showing how “the field of biotechnology is particularly susceptible to commercial ‘uses’ without sales.”<sup>155</sup>

Congress used the microorganism made by a patented process abroad as an example of how “merely stopping importation and non-retail sale of the microorganism after its entry into the country fails to prevent commer-

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147. Sen. Rpt. 100-83 at 49.

148. *Id.* at 30.

149. *Id.* at 49.

150. *Id.* at 30.

151. *Id.* at 49.

152. *Id.*

153. *Id.*

154. *Bio-Technology*, 80 F.3d at 1561.

155. Sen. Rpt. 100-83 at 49.

cial use of the microorganism.”<sup>156</sup> This is an observation that once the self-replicating unpatented microorganism has gained entry into the United States, there is no prohibition on its use in making the final end-product without protection under section 271(g).

The example is analogous to the fact pattern in *Bayer*. Once the research tool is used abroad, the importation or use of the unpatented drug candidate in the United States has no protection unless afforded protection under section 271(g). Without protection, Bayer is free to use the patented process for drug discovery. If the drug candidate later proves to be fit for commercial sales, Bayer will not need to use the patented process to make the commercial product. A comparison between *Bio-Technology* and *Bayer*, on the facts, is developed further in the following section.

#### F. *The Facts in Bayer are Analogous to the Facts in Bio-Technology*

*Bayer* is analogous to *Bio-Technology* because the discovery of an important biological property of a drug candidate is the product and is embodied in the drug itself. Additionally, *Bayer* is analogous to *Bio-Technology* because cloning a gene into a host functions “merely as a predicate process” to “manufacturing” (by expression of) the hormone. Similarly, identifying a drug candidate functions “merely as a predicate process” to “manufacturing” the drug.

The “manufacturing” of biotechnology products is not done by traditional “manufacturing” protocols. Therefore, biotechnological “manufacturing” is merely analogous to traditional “manufacturing.” In *Bio-Technology*, the process patents are directed to the process of genetically modifying the naturally occurring hGH gene.<sup>157</sup> Then the process enables expression of this gene through a bacterial host.<sup>158</sup> Once the gene is inserted directly or indirectly into the bacterial host, the bacterial host naturally expresses the hGH protein product encoded by the hGH gene.<sup>159</sup> Genentech did not synthesize the hGH protein, but rather engineered a microorganism capable of producing a human protein product that could only be previously obtained from the pituitary glands of human cadavers.<sup>160</sup> The patented method is preferable because once the self-replicating bacterial host is engineered, the method provides for a never-ending supply of the hGH protein. In traditional manufacturing terminology, Genentech built the factory which is capable of making the product. Nevertheless,

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156. *Id.*

157. *Bio-Technology*, 80 F.3d at 1557.

158. *Id.*

159. *Id.*

160. *Id.* at 1556-1557.

Genentech has a patent on the whole process including the construction of the “factory” (the engineered bacterium) and the steps taken by the bacterium to produce the “product.”

Analogous to the bacterial host produced by the patented process, the cell line produced by the patented process of Housey function as a population of “factories.” Nevertheless, the method of Housey also protects the exposure of the cell line created to a drug candidate and the comparison of changes between the over-expressing cell line and the original cell line. The patented process of Housey also involves constructing a specific type of cell using bio-engineering methods.<sup>161</sup> This cell is part of a greater population of identical cells called a cell line. The process involves using biotechnological methods to produce a population of cells that have the characteristic of substantial increased expression of a particular protein when compared to the original non-manipulated population of cells.<sup>162</sup> During the performance of the process, the cell line is temporarily phenotypically changed<sup>163</sup> by the application of a drug candidate as compared to the original over-expressing cell line. The question becomes whether the product of this process is the identified drug candidate, the phenotypically changed cell line, or the information gleaned from the exposure of the drug candidate followed by a comparison of the corresponding phenotypically changed cell line.

Information and the phenotypically changed cell lines are not products of the method; rather they are necessary for performing the process. Turning to claim 1 of Housey’s U.S. Pat. No. 4,980,281, the fourth step in the method is to “compar[e] the phenotypic response of the first cell line [over-expressing] to the substance [e.g. a drug candidate] with the phenotypic response of the second cell line.”<sup>164</sup> In order to make a comparison, information about the phenotypic response had to be generated. Conversely, a phenotypical response in the cell line had to occur in order to generate information for comparison.

The discovery of an important biological property of the drug candidate is the product and is embodied in the drug itself. While the drug candidate itself may or may not be patentable depending on whether it meets the novel, useful, and non-obvious standard of patentability, any new

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161. *Bayer*, 340 F.3d at 1369.

162. *Id.*

163. A “phenotypic change” occurs if the application of the drug candidate changes expression of any genes as compared to before the addition of the drug candidate. Therefore, if the drug candidate is an activator or inhibitor of a protein of interest, the change in expression of the protein by the cell is a phenotypic change (response). Biotechterms, <http://biotechterms.org/sourcebook/saveidretrieve.php3?id=1451> (accessed November 17, 2005). “Temporarily” is used because this change is probably not permanent. The drug candidate will at some time cease to be active in the cell.

164. U.S. Pat. No. 4,980,281, claim 1.

treatment utilizing the biological properties of the drug candidate will be patentable.<sup>165</sup> A biological property of the drug candidate is more than mere “information” about the drug candidate, it is the drug candidate. The novel biological property potentially renders the use of the drug as patentable.<sup>166</sup> A property and its corresponding compound are not separable. While discovery of a natural phenomenon is not itself a patentable product, the application of a biological phenomenon embodied in a tangible invention (e.g. a pharmaceutical drug) is.<sup>167</sup>

## V. SOUND ECONOMIC POLICY ENCOURAGES FOREIGN PROTECTION

### A. *The Integra Decision*<sup>168</sup>

#### 1. *Background*

In *Integra*, a scientist (Dr. Cheresch) at Scripps discovered that blocking a certain class of receptors inhibits the process for generating new blood vessels (angiogenesis) and inhibiting the process for generating new blood vessels “showed promise as a means to halt tumor growth.” Merck recognized the importance of this discovery and “hired Scripps . . . to identify potential drug candidates that might inhibit angiogenesis.” Dr. Cheresch’s research suggested that a specific cyclic peptide (i.e. drug candidate) may inhibit angiogenesis. “Merck then entered into an agreement with Scripps to fund the ‘necessary experiments to satisfy the biological bases and regulatory (FDA) requirements for the implementation of clinical trials’ with” the drug candidate. Scripps discovered two derivatives of the drug candidate and conducted several *in vivo* and *in vitro* experiments to determine if

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165. See 35 U.S.C. §§ 101, 102, & 103 (2000).

166. If the drug candidate is found to have a medical use based on the novel biological property, then the use is patentable. See *id.*

167. See *Mackay Radio & Telegraph v. Radio Corp. of Am.*, 306 U.S. 618 (1939) (This case stands for the proposition that while a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be a patentable “invention.”).

168. In *Merck v. Integra Lifesciences*, 125 S. Ct. 2372 (2005), the United States Supreme Court vacated and remanded the *Integra* decision. The Supreme Court held that a patented compound (e.g. drug candidate) used in preclinical studies is protected under section 271(e) as long as there is a reasonable basis for believing the patented compound could be the subject of an FDA submission and the experiments conducted on the patented compound will produce information relevant to an investigational new drug application (IND) or a new drug application (NDA). *Id.* at 2380-84. Thus, the Supreme Court holding provides an exemption for infringement under the safe harbor provision for some preclinical studies. *Id.*

Nevertheless, the *Merck* decision is not directed to research tool patents. The Supreme Court expressly rejects the characterization of the patented compounds in this case as research tools, stating:

any of the derivatives may be suitable for testing in humans. Integra learned of the research, conducted by Scripps in the United States, and believed it infringed one of its patents, and after a failed license negotiation with Merck, this suit was brought.<sup>169</sup>

## 2. Analysis

The issue was “whether pre-clinical research conducted under the Scripps-Merck agreement [was] exempt from liability for infringement of Integra’s patents under [section] 271(e)(1)” because “[t]he Scripps-Merck experiments did not supply information for submission to the United States Food and Drug Administration (FDA), but instead identified the best drug candidate to subject to future clinical testing under the FDA processes.”<sup>170</sup> 35 U.S.C. § 271(e)(1) provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States 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 or veterinary biological products.<sup>171</sup>

The Federal Circuit found that “the context of this safe harbor originally keyed its use to facilitating expedited approval of patented pioneer drugs already on the market” by generic drug companies after the patent expired.<sup>172</sup>

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The Court of Appeals also suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving so-called “research tools” of the complete value of their patents. Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not. See 331 F.3d, at 878 (Newman, J., dissenting) (“Use of an existing tool in one’s research is quite different from study of the tool itself”) [(Now citing to 2003 U.S. App. LEXIS 27796)]. We therefore need not-and do not-express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of “research tools” in the development of information for the regulatory process.

*Id.* at n. 7. I agree that the patent compounds in this case are being used as drug candidates and not as research tools for discovering drug candidates.

The holding of this case will have far reaching effects on the biotechnology industry regarding what preclinical research will fall under the safe harbor provision. Nevertheless, all preclinical research will not be exempted under section 271(e) as the case makes clear. Therefore, domestic protection will still exist for research tools while foreign protection will still be lacking for research tools under section 271(g).

169. *Integra*, 331 F.3d at 863.

170. *Id.* at 865.

171. 35 U.S.C. § 271(e)(1) (2000).

172. *Integra*, 331 F.3d at 867.



### 3. Holding

The Federal Circuit held that “[e]xtending [section] 271(e)(1) to embrace all aspects of new drug development activities would ignore its language and context.”<sup>173</sup> In other words, section 271(e)(1), the safe harbor provision, does not allow a company to use a patented pharmaceutical to identify potential drug candidates hoping to one day bring the drug candidate to clinical trials.<sup>174</sup>

#### B. Economic Impact of *Integra* in Conjunction with *Bayer*

The *Bayer* decision in conjunction with the *Integra* decision encourages foreign and domestic companies to use research tools protected by a United States patent abroad. In *Integra*, the Federal Circuit held that 35 U.S.C. § 271(e) is not a true “experimental use” exception.<sup>175</sup> Under *Integra*, a company cannot use, without authorization, a patented research tool in the United States to identify a potential drug candidate in the hopes of subjecting the drug candidate to clinical trials under the regulation of the FDA.<sup>176</sup> Under *Bayer*, a company can use, without authorization, a patented research tool abroad to identify a potential drug candidate.<sup>177</sup>

In strong support for domestic enforcement of patented research tools, the Federal Circuit stated:

For example, expansion of [section] 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents. After all, patented tools often facilitate general research to identify candidate drugs, as well as downstream safety-related experiments on those new drugs. Because the downstream clinical testing for FDA approval falls within the safe harbor, these patented tools would only supply some commercial benefit to the inventor when applied to general research. Thus, exaggerating [section] 271(e)(1) out of context would swallow the whole benefit of the *Patent Act* for some categories of biotechnological inventions.<sup>178</sup>

Despite the strong support for biotechnology research tool patents in *Integra*, this protection cannot be reconciled with the *Bayer* decision. Strong

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173. *Id.*

174. *Id.*

175. 331 F.3d at 870; see 35 U.S.C. § 271(e)(1).

176. 331 F.3d at 874.

177. 340 F.3d at 1377.

178. *Integra*, 331 F.3d at 867.

domestic protection of research tools is incompatible with a lack of foreign protection because companies will be encouraged to perform pre-clinical research abroad.

Therefore, some foreign and domestic companies were correct in

believ[ing] they have found a lawful way to use the patented processes, without paying royalties, simply by employing the methods in a foreign country in which the patentee does not have patent protection and then providing the relevant data to a customer (or subsidiary) in the U.S., who then proceeds to construct or use the molecule identified by the patented method—but without ever using the method itself in the U.S.<sup>179</sup>

The lack of foreign protection prevents “many biotechnology companies [who] based their business models on the presumed ability to get royalties on pharmaceutical products developed using their patented drug discovery tools” from collecting such royalties.<sup>180</sup>

## VI. CONCLUSION

Section 271(g) should be broadened to encompass as an infringing act the use of a drug candidate in the United States when discovered by a patented research tool used abroad. Specifically, this article proposes that the courts interpret the word “product” to cover the discovery of the drug as embodied by the actual drug. The phrase “made by” should extend to *all* steps taken to bring a drug to market rather than be limited to physical “manufacturing.”

The Federal Circuit correctly reasoned that information *per se* is not a “product” and that “it is beyond dispute that a drug is a physical product” under section 271(g). Further, that “made by” is ambiguous according to the plain meaning of the statute and can be interpreted broadly to encompass more than traditional “manufacturing.” Additionally, the Federal Circuit recognized that the legislative history of section 271(g) “does not *affirmatively* suggest an intent to limit coverage to manufactured ‘articles.’”

Section 271(g) is broader in scope than section 287(b). The Federal Circuit inference that “made by” is equivalent to “manufactured” under section 287(b) is not justified. Section 287(b) cannot be used to limit the scope of section 271(g) because section 271(g) was enacted to address the concerns of importers of goods manufacturers abroad. On the other hand,

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179. See Thayer, *supra* n. 3, at 87.

180. Groombridge, *supra* n. 2, at 462.

section 271(g) also provides a remedy when the product is used or sold in the United States after a manufacturer used the patented process abroad without authorization. Bayer is a manufacturer, not an importer, who used a patented process abroad without authorization.

Congress crafted the exception in section 271(g) narrowly because Congress wanted the courts to determine the scope of section 271(g) without being unnecessarily hampered. The Federal Circuit was aware that Congress gave the courts the duty to determine the scope of section 271(g). Further, Congress established a two-part test to help courts interpret the scope of the exceptions to section 271(g). The two-part test is consistent with a broad interpretation of section 271(g). Identifying a drug candidate would not be exempted from infringement under the congressional test. The identification of the drug candidate using the patented process was the only way to make the identification and the drug candidate will not change upon use in the United States.

Congress enacted section 271(g) to broaden protection consistent with ITC protection because section 271(g) provides remedies to parties that could not seek relief through the ITC. Additionally, Congress wanted the federal courts to provide the patent-type infringement analysis the federal courts are in the best position to provide. Therefore, in enacting section 271(g), Congress contemplated a broader statutory scheme and thus did not merely add additional remedies that were not available under the ITC. ITC protection attempts to cover any physical product associated with a patented process used abroad and section 271(g) should be consistent with ITC protection. A drug candidate is a physical product associated with the use of patented research tool abroad.

Congress enacted section 271(g) to prevent commercial uses of biotechnology process patents abroad. Congress wanted the courts to determine the scope of “made by” and therefore Congress specifically left to the courts the task to expand section 271(g) interpretation consistent with the goals of section 271(g) enactment. Congress intended section 271(g) to apply to commercial uses of a biotechnology patented process abroad even if the product of the use will not be manufactured by the process directly. The legislative history shows that Congress expressly anticipated the fact pattern in *Bio-Technology*. A drug candidate is not “manufactured” directly by a patented research tool. Nevertheless, the intention of Congress was to protect the commercial use of a research tool under section 271(g).

*Bayer* is analogous to *Bio-Technology* because the discovery of an important biological property of a drug candidate is the product and is embodied in the drug itself. Additionally, *Bayer* is analogous to *Bio-Technology* because cloning a gene into a host functions “merely as a predicate process” to “manufacturing” (by expression of) the hormone.

Similarly, identifying a drug candidate functions “merely as a predicate process” to “manufacturing” the drug. Further, the “manufacturing” of biotechnology products is not done by traditional “manufacturing” protocols; therefore biotechnological “manufacturing” is merely analogous to traditional “manufacturing.” The phrase “made by” should be interpreted to encompass more than physical “manufacturing,” because a biotechnological product is not “manufactured” in the traditional sense of the word.

Sound economic policy encourages broadening the scope of protection under 271(g). Despite the strong support for biotechnology research tool patents in *Integra*, this protection cannot be reconciled with the *Bayer* decision. Strong domestic protection of research tools is incompatible with a lack of foreign protection because more companies will be encouraged to perform pre-clinical research abroad.