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Michael Delmas Plimier

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## GENENTECH, INC. V. NOVO NORDISK & UNIVERSITY OF CALIFORNIA V. ELI LILLY AND CO.

*By Michael Delmas Plimier*

The Constitution states the policy justification behind the patent system, giving Congress the authority “to promote the Progress of Science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>1</sup> Patents represent a bargain between society and the inventor. The inventor gives information to the public and receives a monopoly for a period of time. This tradeoff must be balanced. If inventors do not receive enough reward for sharing their inventions, they will choose not to disclose their inventions or not to invest in research. This will slow down the production and dissemination of innovations and progress. On the other hand, if inventors are allowed to claim more than what they have disclosed, future inventions may not be undertaken because the first inventor would reap the benefits of the later work.<sup>2</sup>

Part of the balancing act is performed through the first paragraph of section 112 of the Patent Act, which requires both enabling disclosure and a written description of the claimed invention.<sup>3</sup> Written description and enablement are distinct requirements, but they share the function of limiting the scope of the inventor’s claim.

The enablement requirement ensures the public gets something in exchange for patent rights: knowledge of how to make and use the invention. Because one cannot claim something which has not been enabled,<sup>4</sup>

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1. U.S. CONST. art. I, § 8, cl. 8.

2. “Case law concerning biotechnology patents reflects the tension between the need for broad claims to meaningfully reward valuable (often medically significant) advances and the concern that granting broad claims will hinder further advances or disproportionately reward those who make small, but timely contributions.” Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 4 FED. CIRCUIT B.J. 243, 250 (1994).

3. “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ....” 35 U.S.C. § 112 (1994).

4. The first paragraph section 112 “requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to per-

the inventor is prevented from getting the rights to technology without sharing information on how to make and use it. The enabling disclosure does not have to lay out exactly how to make and use the claimed invention. All that is needed is enough information to allow those with skill in the art to make or use the invention without undue experimentation.<sup>5</sup>

In contrast, the written description does not necessarily provide the public with information of value. Instead, it acts to limit the breadth of the inventor's claims.<sup>6</sup> Only what has been described can be claimed. The description must be clear enough to show that the inventor possessed the invention.<sup>7</sup> The written description requirement prevents inventors from claiming what they have not envisioned. One can enable without describing, and describe without enabling. Together, the requirements set bounds on what can be claimed.

The holdings of *Genentech, Inc. v. Novo Nordisk*<sup>8</sup> and *University of California v. Eli Lilly and Co.*<sup>9</sup> illustrate the Federal Circuit's concern with granting overbroad patents and its use of the enablement and written description requirements to prevent this. Although the consequences of these cases have yet to be felt, they may reduce the incentive to invent because patent protection would require a large disclosure and result in only narrow protection.

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sons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970).

5. "That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1212, 18 U.S.P.Q.2d 1016, 1026 (Fed. Cir. 1991).

6. "Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551, 211 U.S.P.Q. 303, 321 (3d Cir. 1981).

7. "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

8. 108 F.3d 1361, 42 U.S.P.Q.2d 1001 (Fed. Cir. 1997) [hereinafter *Novo II*].

9. 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) [hereinafter *Lilly II*].

## I. ENABLEMENT: *GENENTECH V. NOVO NORDISK*

### A. Previous Opinions

At issue was the validity and infringement of Genentech's patent claiming genetically engineered human growth hormone (hGH). Two methods of making hGH were involved. The first is the direct expression of hGH. This is where DNA codes for the hGH protein alone.<sup>10</sup> The second, the method Novo Nordisk (Novo) used, is the cleavable fusion expression of hGH. In this procedure, DNA codes for hGH bonded to other peptides (protein fragments), thereby forming a protein that is larger than hGH alone. These extra peptides are then removed using an enzyme,<sup>11</sup> resulting in essentially the same product as the first method: the hGH protein.<sup>12</sup>

Litigation began when Novo brought an action in the Southern District of New York seeking a declaratory judgment that Genentech's patent 4,601,980 (the '980 patent) was not being infringed and was invalid.<sup>13</sup> The district court ruled Genentech would likely succeed on the merits with regard to infringement and validity.<sup>14</sup>

On appeal, the Federal Circuit reversed.<sup>15</sup> Judge Lourie ruled that there was no infringement of the '980 patent, because it claimed only the direct expression of hGH—not the cleavable fusion expression which Novo used.<sup>16</sup>

The case returned to the district court where Genentech received an injunction against Novo under its newly issued U.S. Patent No. 5,424,199 ('199 patent).<sup>17</sup> This patent has the same specification as the '980 patent, but explicitly claims the cleavable fusion expression of hGH, a fact Novo conceded.<sup>18</sup> Its non-infringement defense gone, Novo argued that the pat-

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10. See *Novo II*, 108 F.3d at 1363, 42 U.S.P.Q.2d at 1002-03.

11. This removal of the extra peptides with enzymes is the "cleavage."

12. See *id.* at 1363, 42 U.S.P.Q.2d at 1003.

13. See *Novo Nordisk of North America v. Genentech, Inc.*, CIV. A. No. 94 CIV. 8634 (CBM), 1995 WL 512171, at \*1 (S.D.N.Y. Aug. 28, 1995).

14. See *id.* at \*2.

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

16. See *id.* at 1371, 37 U.S.P.Q.2d at 1779.

17. See *Genentech, Inc. v. Novo Nordisk*, 935 F. Supp. 260, 285 (S.D.N.Y. 1996) [hereinafter *Novo I*].

18. See *id.* at 265.

ent was not enabling,<sup>19</sup> that it did not contain enough information for one skilled in the art to practice the invention without undue experimentation.<sup>20</sup>

A reasonableness standard is used to decide whether undue experimentation is required.<sup>21</sup> The court used the test laid out in *In re Wands*,<sup>22</sup> which provided a list of eight factors for courts to consider. They are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.<sup>23</sup>

Under this test, the court concluded undue experimentation was not needed to practice the invention.<sup>24</sup> The court found that when combined with the skill of the art, the disclosure was adequate to teach how to add the extra protein sequence to the hGH.<sup>25</sup> The use of trypsin, the enzyme used to cleave the extra proteins, was found to be well-known.<sup>26</sup> The court also found that the conditions for using trypsin were listed in the package inserts included with purchases of trypsin as well as in standard references.<sup>27</sup>

## B. United States Court of Appeals, Federal Circuit

Not only did the Federal Circuit vacate the injunction, it also ruled the patent invalid for lack of enablement.<sup>28</sup> Judge Lourie ruled it would require undue experimentation for an ordinary person skilled in the art to practice the claimed invention.<sup>29</sup>

The court found that there was not enough information in the specification as to what extra proteins should be added to the hGH.<sup>30</sup> Genentech's testimony established that one skilled in the art could make a short

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19. Novo also argued the written description requirement was not met, but as that issue was not dealt with on appeal, it is not dealt with in this comment. *See Novo II*, 108 F.3d at 1368, 42 U.S.P.Q.2d at 1007.

20. *See Novo I*, 935 F. Supp. at 271.

21. *See id.* at 273.

22. 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

23. *See id.* at 737, 8 U.S.P.Q.2d at 1404.

24. *See Novo I*, 935 F. Supp. at 273.

25. *See id.* at 274.

26. *See id.*

27. *See id.*

28. *See Novo II*, 108 F.3d at 1368, 42 U.S.P.Q.2d at 1007.

29. *See id.*

30. *See id.* at 1366, 42 U.S.P.Q.2d at 1005.

sequence of amino acids to be added, but did not discuss how much experimentation would be needed to create the longer sequence which was actually necessary for the cleavable fusion expression of hGH.<sup>31</sup> The specification did not say which extra proteins should be attached to the hGH that would subsequently be cleaved.<sup>32</sup> The court ruled that to find out would take extensive experimentation.<sup>33</sup>

The court also ruled that the use of trypsin for cleaving proteins was not known. Novo's testimony established that at the time of the application, trypsin was only used to digest proteins, not to cleave them.<sup>34</sup> Genentech's reference to a British patent for information on using trypsin as a cleaving agent was found to be unresponsive, since the reference actually says that trypsin would not be appropriate in the cleavable fusion expression of hGH.<sup>35</sup> No reaction conditions for the use of trypsin in cleavable fusion expression were included in the specification.<sup>36</sup>

Genentech argued that the knowledge of one skilled in the art would fill the gaps in the specification as to the extra proteins and the use of trypsin.<sup>37</sup> The court did not agree, and did not think the skill of the art was the proper focus.<sup>38</sup> Instead, the court looked at what was in the specification.<sup>39</sup> Minor details could be left out, but if no specific starting material or reaction conditions are given, undue experimentation is required.<sup>40</sup> The court also concluded that if the extra peptides and method of cleavage were within the skill of the art, they would have been disclosed in the specification.<sup>41</sup>

Judge Lourie also used the fact that no one was able to use cleavable fusion expression to produce any human proteins for nearly a year, or to produce hGH using this method for five years after the filing date, as evidence it was not within the skill of the art.<sup>42</sup>

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31. *See id.* at 1366, 42 U.S.P.Q.2d at 1005.

32. *See id.* at 1365, 42 U.S.P.Q.2d at 1004.

33. *See id.* at 1367, 42 U.S.P.Q.2d at 1006.

34. *See id.* at 1365, 42 U.S.P.Q.2d at 1004.

35. *See id.*

36. *See id.*

37. *See Novo II*, 108 F.3d at 1365, 42 U.S.P.Q.2d at 1004.

38. *See id.* at 1366, 42 U.S.P.Q.2d at 1005.

39. *See id.*

40. *See id.*

41. *See id.* at 1367, 42 U.S.P.Q.2d at 1006.

42. *See id.*

### C. Discussion of *Novo*

The ruling seems to be based on a concern that the '199 patent tries to claim too much. The '199 patent uses the same specification as the '980 patent, changing the claim to include cleavable fusion expression of hGH.<sup>43</sup> Judge Lourie ruled the specification for the '980 patent lays out and then solves the problem of getting hGH without other proteins—the direct expression of hGH.<sup>44</sup> The specification mentions cleavable fusion expression, but this is not its focus.

There have been problems with nebulous specifications being allowed to mature to patents, not the least of which is allowing a patent holder to gain a large financial windfall without disclosing any useful information.<sup>45</sup> By limiting allowable claims to what the specification is clearly directed to, these problems will be avoided. It will ensure the patent trade is not one-sided, with patent holders giving little for their patent rights. In this case, it means limiting the claims to the direct expression of hGH.

However, the decision also creates problems. The question of how much experimentation is undue has long been fuzzy, with a reasonableness standard being applied to complex fact patterns. In 1988, the Federal Circuit tried to bring more structure to the test: to make it easier to apply and more predictable. It set out the list of eight *Wands* factors to accomplish this. These factors gave some guidance for what had to be included in patent specifications.

The Federal Circuit is no longer spending much time looking at whether or not undue experimentation is required.<sup>46</sup> In *Amgen v. Chugai*,<sup>47</sup> the court said that, "it is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory."<sup>48</sup> The factors have been further undercut to the point of being ignored in subsequent Federal Circuit cases.<sup>49</sup>

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43. See *Novo I*, 935 F. Supp. at 265.

44. See *Novo II*, 108 F.3d at 1366, 42 U.S.P.Q.2d at 1005.

45. See generally M. Scott Carey, *Ford Motor Co. v. Lemelson*, 13 BERKELEY TECH. L.J. 219 (1998).

46. "Another trend illustrated by *Amgen*, *Vaeck*, and *Goodman* is the refusal of the CAFC to conduct an extensive inquiry into the various undue experimentation factors ...." John C. Todaro, *Enablement in Biotechnology Cases After In Re Goodman*, 5 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1, 39 (1994).

47. 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

48. *Id.* at 1213, 18 U.S.P.Q.2d at 1027.

49. The *Wands* factors were not mentioned in the enablement discussion in *In re Wright*, 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993) or *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993).

The trend away from the *Wands* factors continues in this case. Judge Lourie made no mention of *Wands* or of anything specific a court should look at when deciding the issue of undue experimentation. The decision gives no help to future patent applicants. By ignoring *Wands*, the Federal Circuit leaves biotech patent applicants wondering what is needed in their specification.<sup>50</sup>

Unclear standards also could reduce the value of patents. Without clear standards, no patent will be clearly valid, and litigation challenging them may increase. Even if the patent is upheld, this possible litigation would increase the patent holder's costs and therefore decrease the benefit inventors receive from patents.

Judge Lourie does not address the fact that patent specifications often disclose more than one patentable invention. That the specification was already found to support one patent does not warrant the automatic conclusion that it does not support others; full consideration should be given to the question, with the reasoning laid out in the opinion. This decision reversing the district court's ruling is basically conclusory. The court held that the specification provided enablement for direct expression of hGH but only suggested cleavable fusion expression without enabling it. In doing so, the court discounted testimony of the skill in the art and treated the lack of explicit enabling directions as evidence it wasn't in the prior art. "A specification need not disclose what is well known in the art."<sup>51</sup> Much of Genentech's argument was that the gaps in the specification would be filled by the knowledge practitioners had. The court dismissed this line of reasoning; "Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement."<sup>52</sup>

If the courts place little weight on evidence of what the skill in the art is, applicants will not be able to rely on the skill in the art to fill gaps in the specification. This will require applicants to include information that they believe is possessed by those skilled in the art, forcing applicants to disclose more in the specification than they should have to.

Judge Lourie's stated that, "if the disclosure of a useful conjugate protein and the method for its cleavage were so clearly within the skill of the art, it would have been expressly disclosed in the specification."<sup>53</sup>

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50. "[Recent] CAFC decisions will leave applicants guessing as to what constitutes undue experimentation." Todaro, *supra* note 45, at 39.

51. *Novo II*, 108 F.3d at 1366, 42 U.S.P.Q.2d at 1005.

52. *Id.*

53. *Id.* at 1367, 42 U.S.P.Q.2d at 1006.

This seems to directly contradict the rule that if something is well known in the art, it doesn't have to be disclosed. Further, if an applicant does not disclose something because it is clearly within the skill of the art, Judge Lourie's reasoning would apparently take this as evidence that it is not within the skill of the art. The only way around this problem is to disclose everything involved in producing the invention, greatly increasing the size of specifications.

## II. WRITTEN DESCRIPTION: *UNIVERSITY OF CALIFORNIA V. ELI LILLY & CO.*<sup>54</sup>

### A. District Court

The Regents of the University of California (UC) brought this action in the Northern District of California against Eli Lilly & Co. (Lilly) for infringement of patent 4,652,525 (the '525 patent).<sup>55</sup> It was transferred to the Southern District of Indiana on Lilly's motion.<sup>56</sup> Lilly argued that the patent claims for human, mammalian, and vertebrate insulin DNA were invalid due to lack of written description.<sup>57</sup>

The '525 patent claims rat, human, mammalian, and vertebrate insulin DNA. Naming a DNA along with instructions on how to produce it is not enough to satisfy the written description requirement.<sup>58</sup> A description of the DNA itself is needed, such as nucleotide sequence. The '525 patent specification does include the nucleotide sequence for rat insulin DNA. The issue was whether giving the nucleotide sequence for the species, rat insulin DNA, is enough to allow the inventor to claim: (1) the genera of mammalian and vertebrate insulin DNA, which contain the species of rat insulin DNA; and (2) another species, human insulin DNA, within the genera.<sup>59</sup> The court concluded it did not.<sup>60</sup>

The court pointed out that the rat insulin DNA sequence did not give an exact description of the human insulin DNA. Four codons are differ-

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54. Although there were several issues in this case, this comment only deals with the written description requirement with respect to U.S. Patent No. 4,652,525. The case also dealt with U.S. Patent No. 4,431,740. It addressed jurisdiction, venue, and enforceability with respect to both patents, and whether U.S. Patent No. 4,431,740 was infringed. See *Lilly II*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398.

55. See *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225, 1227 (S.D. Ind. 1995) [hereinafter *Lilly I*].

56. See *id.*

57. See *id.* at 1241.

58. See *id.* at 1240.

59. See *id.*

60. See *id.* at 1241.

ent.<sup>61</sup> Therefore, the court concluded the rat DNA sequence was not the precise definition of the human DNA sequence required under section 112 of the Patent Act. The court applied the same reasoning to the mammalian and vertebrate insulin DNA. The court ruled there are thousands of species within the vertebrate and mammalian genera, with insulin genes that are not identical, so the rat insulin DNA is not sufficient to describe them.<sup>62</sup>

### **B. United States Court of Appeals, Federal Circuit**

On appeal, the Federal Circuit upheld the ruling.<sup>63</sup> The court first dealt with claim 5, for human insulin DNA.<sup>64</sup> The specification tells how to produce this DNA,<sup>65</sup> but telling how to do something (enablement) is not the same as providing a written description.<sup>66</sup> The court said that although the specification includes the amino acid sequence of human insulin, this is not a written description either.<sup>67</sup> Disclosing enough information to make a claim obvious does not mean the written description requirement is satisfied.<sup>68</sup> The amino acid sequence of a protein plus the method for generating the DNA for that protein does not make the DNA obvious.<sup>69</sup> The court ruled that since rendering an invention obvious is not necessarily enough to meet the written description requirement, and the information given is not enough to render the invention obvious, the information given did not meet the written description requirement.<sup>70</sup>

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61. *See id.* A codon is a group of three DNA nucleotides that codes for one amino acid. There are 64 possible codons coding for 20 different amino acids—amino acids can be coded for by more than one codon. *See* Dr. Shaun D. Black, *The Genetic Code* (visited Feb. 11, 1998) <<http://pegasus.uthct.edu/ResUTHCT/Investigators/Sblack/geneticd.html>>.

62. *See Lilly I*, 39 U.S.P.Q.2d at 1241.

63. *See Lilly II*, 119 F.3d at 1559, 43 U.S.P.Q.2d at 1400.

64. *See id.* at 1567, 43 U.S.P.Q.2d at 1404.

65. Adequate enabling disclosure for the '525 patent was not challenged in this case or in the court below. *See Lilly I*, 39 U.S.P.Q.2d 1225; *Lilly II*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398.

66. *See Lilly II*, 119 F.3d at 1567, 43 U.S.P.Q.2d at 1405.

67. *See id.* at 1567, 43 U.S.P.Q.2d at 1405. Since amino acids can be coded for by more than one codon, the amino acid sequence does not tell one what the nucleotide sequence is. For example, the nucleotide sequences of CGT, CGC, CGA, CGG, AGA, and AGG all code for the same amino acid, Arg. So an amino acid sequence will have many possible nucleotide sequences that code for it. *See* Dr. Shaun D. Black, *The Genetic Code* (visited Feb. 11, 1998) <<http://pegasus.uthct.edu/ResUTHCT/Investigators/Sblack/geneticd.html>>.

68. *See Lilly II*, 119 F.3d at 1567, 43 U.S.P.Q.2d at 1405.

69. *See id.*

70. *See id.*

The court made similar short work of claims 1, 2, 6, and 7, for vertebrate insulin DNA, and claim 4, for mammalian insulin DNA. UC argued that the written description of a species within a genus is enough to claim that genus.<sup>71</sup> The written description of rat insulin DNA would therefore allow UC to claim the genera of mammalian and vertebrate insulin DNA. The court acknowledged that it is possible to claim a genus without providing a written description for each species within the genus.<sup>72</sup> However, to do this requires a precise definition of the genus, such as which structural features characterize the genus.<sup>73</sup> The court ruled "Mammalian insulin DNA" is a functional description, not a description of the specific structural aspects that define the genus.<sup>74</sup> A functional description describes what the thing does, not what it is.<sup>75</sup> The court said that description of a DNA, "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA."<sup>76</sup> Since only the nucleotide sequence of rat insulin DNA and functional genera are given in the specification, the court ruled the written description requirement had not been met.

### C. Discussion of *Lilly*

The decision is doctrinally correct. Human, mammalian, and vertebrate insulin DNA are not described in the specification except by function. According to *Fiers v. Revel*,<sup>77</sup> a functional description is not enough; the DNA must be described more precisely.<sup>78</sup>

Rat insulin DNA has a nucleotide sequence very close to that of human insulin DNA.<sup>79</sup> It is conceivable that the court could have decided that the dissimilarities are small enough for the rat DNA nucleotide sequence to serve as written description for the human insulin DNA claims. The court could even have said that mammalian and vertebrate insulin DNA were close enough to rat insulin DNA to have been adequately de-

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71. See *id.* at 1567-68, 43 U.S.P.Q.2d at 1405.

72. See *id.* at 1568, 43 U.S.P.Q.2d at 1405.

73. See *id.* at 1568, 43 U.S.P.Q.2d at 1406.

74. See *id.*

75. See *id.*

76. *Id.* at 1569, 43 U.S.P.Q.2d at 1406.

77. 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993).

78. See *id.* at 1169, 25 U.S.P.Q.2d at 1604-05.

79. "The human insulin cDNA, for example, differs from the rat insulin cDNA by four codons." *Lilly I*, 39 U.S.P.Q.2d at 1241. There are 111 codons in the DNA sequence for human insulin. See *PubMed Nucleotide Query* (visited Feb. 2, 1998) <<http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?uid=186431&form=6&db=n&Doptg>>.

scribed. However, if the court did this, there would be the risk of allowing the patentee to claim a genus not actually described. The actual DNA sequences were not known and the genera claimed were based on taxonomy, not necessarily on common insulin DNA properties.<sup>80</sup> UC did not provide any information as to what feature the various insulin DNA sequences have in common, so the court had no basis on which to rule that the rat DNA sequence was enough to define the genus.<sup>81</sup> Since there was no evidence given as to how similar the rat insulin DNA structure was to human, mammalian, and vertebrate insulin DNA, the ruling was proper.

It remains to be seen whether the written description requirement would be fulfilled for broader genetic engineering patents if a court is given information defining a genus's structural similarity to a species. It is also unclear how rigorous a standard the information would have to meet.

The decision creates potential problems for DNA patents. With the difference of four codons out of over a hundred meaning the difference between infringement and non-infringement, the ruling gives only very narrow protection to genetic engineering patents. Because not every codon matters in the function of the protein, some could be changed and the patent dodged very easily.<sup>82</sup> Patents held to be only as broad as the specific DNA nucleotide sequence disclosed have very little value.<sup>83</sup> Competitors may be able to make the product without spending much on research just by making a minor change in the DNA. With lower research costs, the competitor could charge a lower price. The inventor will have

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80. "The principles upon which this taxonomic system is based are not necessarily coincident with suitability for the disclosed genetic manipulation." Brian P. O'Shaughnessy, *The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure Within the Unpredictable Arts*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 147, 222 (Autumn, 1996).

81. "The proper inquiry is whether there is a key feature common to those members of the claimed genus and associated with the utility alleged." *Id.* at 210.

82. Biotechnology is a field where functionally equivalent variants abound. Despite the fact that at critical loci a single base change in a nucleic acid sequence or a single amino acid substitution in a protein can drastically alter function, many non-critical loci occur which tolerate all sorts of sequence variations without affecting function.

Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENV. U. L. REV. 127, 133 (1991).

83. "A claim limited to one sequence, or even half a dozen functionally equivalent sequence variants, is virtually worthless if a competitor can simply make another functional variant outside the claim ... literally thousands of functionally equivalent sequence variants exist ... defining each of them is an impossible task ...." *Id.* at 133.

no incentive to invent, since the costs of research could not be recouped: biotechnology progress will likely slow.

The '525 patent has been published and tells how to make and use human insulin DNA. UC has given valuable information to society. By ruling that the patent is so narrow as to only include rat insulin DNA, UC received little in return. The incentive for future applicants in UC's position to file a patent is diminished, since UC gave up information and got nothing in return.

One may ask if the written description requirement should be eased or done away with in DNA cases. Insulin in many species is extremely similar.<sup>84</sup> Their DNAs may be similar enough that perhaps going through and finding the nucleotide sequences of many species would be repetitive, add little of value to the store of knowledge, and waste resources which could be better used for new research.<sup>85</sup> The written description requirement has been confusing.<sup>86</sup> Enablement can serve the role of preventing inventors from claiming too much.<sup>87</sup> Since it is confusing and perhaps unnecessary,<sup>88</sup> the removal of the written description requirement is something to be considered if the current rule turns out to allow only patents that are so narrow that they inhibit the pace of biotech research.

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84. Human and bovine insulin, for example, are similar enough that until the recent development of recombinant methods for getting human insulin, diabetics relied on bovine insulin. See *LabSpec - Drugs* (visited Feb. 18, 1998) <[http://labspec.co.za/\\_drugs.htm](http://labspec.co.za/_drugs.htm)>.

85. For insulin DNA nucleotide sequences of various species (each web site corresponds to a separate species), see *PubMed Nucleotide Query* (visited Feb. 19, 1998) <<http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?uid=202471&form=6&db=n&Dopt=g>>, <<http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?uid=191273&form=6&db=n&Dopt=g>>, and <<http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?uid=467970&form=6&db=n&Dopt=g>>.

86. With respect to the written description requirement: "[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 U.S.P.Q.2d 1111, 1114 (Fed. Cir. 1991).

87. "And, of course, the regular enablement requirement seeks to relate patent scope to the underlying value of the patentee's disclosure." ROBERT P. MERGES, *PATENT LAW AND POLICY* 714 (2d ed. 1997).

88. "One may wonder what purpose a separate 'written description' requirement serves ...." *Vas-Cath*, 935 F.2d at 1560, 19 U.S.P.Q.2d at 1114. "The usual argument - that [the written description] gives notice to competitors concerning the scope of the applicant's intended claim scope - seems to miss the fact that parent patent applications are not disclosed." MERGES, *supra* note 84, at 714.

### III. CONCLUSION

Read in combination, these two Federal Circuit cases illustrate Judge Lourie's concern with preventing overly broad patents. Only claims that are explicitly and completely enabled in the disclosure will be allowed. There is a de-emphasis on allowing outside information to fill in the enablement gaps. Only the specific DNA described by a nucleotide sequence will be covered by claims. These factors lead to very specific, narrow patents.

DNA patents are also in a state of uncertainty. The Federal Circuits standards for enablement and undue experimentation are unclear. The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless. This may change if applicants develop a method for describing a category of DNA without having to give each nucleotide sequence.

If it does not change, the pace of fundamental biotechnology research may slow. However, if narrow patents create a slowdown in fundamental research, it should be at least somewhat offset by an increase in the development of specific uses for fundamental concepts.<sup>89</sup> Broad patents allow pioneering researchers to gain most of the rewards from their research, and therefore have more incentive for conducting it. Narrow patents mean that pioneering researchers will see the rewards go to those who come later with specific applications of the technology, therefore giving incentives to develop them.<sup>90</sup> Of course, there is a possibility that the patents would be so narrow as to worthless, which would provide no incentive for any research. It remains to be seen whether the current state of DNA patent law strikes the right balance between broad and narrow patents, between fundamental research and specific applications.

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89. "Broad patents encourage fundamental research, and narrow patents encourage development." ROBERT COOTER & THOMAS ULEN, *LAW AND ECONOMICS* 121 (2d ed. 1997).

90. To illustrate, suppose that an investment of \$100,000 in research yields a pioneering invention that has no commercial use. Subsequently, an investment of \$50,000 in development yields an improvement that has commercial value of \$1 million. If the law grants broad patents, a patent for the pioneering invention would also cover the application, but if the law grants narrow patents, separate patents would be required for the pioneering invention and the application.

*Id.* at 121.

