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Emanuel Vacchiano

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# IT'S A WONDERFUL GENOME: THE WRITTEN-DESCRIPTION REQUIREMENT PROTECTS THE HUMAN GENOME FROM OVERLY-BROAD PATENTS<sup>1</sup>

EMANUEL VACCHIANO\*

## INTRODUCTION

George Bailey of Bedford Falls, New York, made it to college after all!<sup>2</sup> In fact, Doctor Bailey embarked on a great adventure, joining thousands of others who are crossing a vast, unknown sea attempting to discover its hidden secrets which may reveal the cures to many of today's most deadly diseases.<sup>3</sup> Fortunately, George did not leave Bedford Falls for his adventure. For this adventure is the Human Genome Project and the modern-day explorers are scientists like Dr. Bailey, who received his Ph.D. from the State University and set up a research lab in Bedford

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1. After submission of this Comment for publication, the United States Patent & Trademark Office (PTO) issued interim guidelines for examination of patent applications under the written description requirement. Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement, 63 Fed. Reg. 32,639 (1998). Additionally, on October 6, 1998, the PTO issued U.S. Patent No. 5,817,479 which some claim is the first EST patent. Young et al., U.S. Patent No. 5,817,479. See *Incyte Pharma Gets Patent On Human Kinase Genes*, Dow Jones News Service, Nov. 4, 1998 (discussing Incyte's announcement that it had obtained a patent covering expressed sequence tags). But see *Patent on Gene Fragments Sends Researchers a Mixed Message*, 396 NATURE 499, 499 (1998) (discussing the position of the PTO that this is not an EST patent).

\* J.D. Candidate, Jan. 2000. Special thanks are due to Donald Reynolds, Dr. Patrick Halloran, and Daniel Boehnen for their critical reviews of drafts of this Comment.

2. See *IT'S A WONDERFUL LIFE* (RKO and Liberty Films 1946) [hereinafter *WONDERFUL LIFE*] (focusing on the life of a fictional generous and kind person, George Bailey). The *Wonderful Life* movie does not involve a Human Genome Project as discussed in this Comment. The author uses some of the characters and themes from the movie to create a more enjoyable reading experience.

3. See generally Shannon Brownlee et al., *Tinkering with Destiny*, U.S. NEWS & WORLD REP., Aug. 22, 1994, at 59 (discussing the implications of the discovery of the BRCA1 breast cancer susceptibility gene and future genomic research on cancer treatment and diagnosis); Philip Elmer-Dewitt, *The Genetic Revolution*, TIME, Jan. 17, 1994, at 46 (discussing the human genome project and the practical implications of human genome discoveries).

Falls to unmask the secrets of human life by using the power of recombinant DNA technologies.<sup>4</sup>

In 1991, based on results of human genome research, the National Institutes of Health (NIH) announced that it planned to file patents on small, incomplete sequences of genes called "expressed sequence tags" (ESTs), derived from the human genome.<sup>5</sup> A high-profile international debate ensued.<sup>6</sup> Although many patents had issued on deoxyribonucleic acid (DNA) segments from the human genome which encoded proteins, this was the first time anyone attempted to obtain a patent on thousands of segments of the human genome which did not encode entire functional proteins and which were obtained by a routine mass-sequencing method.<sup>7</sup> The NIH eventually abandoned these applications in the face of PTO rejection.<sup>8</sup> This seemed to establish precedent that such DNA fragments were unpatentable. However, several small biotechnology (biotech) companies resumed the effort by applying for patents on thousands of ESTs they had isolated.<sup>9</sup>

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4. See Lee Rowen et al., *Sequencing the Human Genome*, 278 SCIENCE 605, 605-607 (1997) (discussing the current status and future challenges of the human genome project); G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AIPLA Q. J. 27, 28-46 (1994) (discussing the history and technologies of the human genome project); see also Elmer-Dewitt, *supra* note 3, at 48-49 (discussing briefly the goal of the human genome project and Francis Collins, one of the scientists leading this project).

5. See, e.g., *NIH Seeks Second Controversial Gene Patent*, REUTERS N. AM. WIRE, Feb. 12, 1992, available in LEXIS, News Library, ARCNEWS File (reporting on a news conference in which officials at the NIH announced the filing of a patent covering thousands of ESTs).

6. See Reid G. Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization*, 257 SCIENCE 908, 908-13 (1992) (discussing issues related to patenting ESTs and discussing NIH's reasons for filing patent applications covering ESTs); Thomas D. Kiley, *Patents on Random Complementary DNA Fragments?*, 257 SCIENCE 915, 915-18 (1992) (discussing problems related to patenting ESTs); see also Rebecca S. Eisenberg, *Genetics and the Law: The Ethical, Legal, and Social Implications of Genetic Technology and Biomedical Ethics: Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557, 558-59 (1996) [hereinafter *Genetics and the Law*] (discussing the debate that ensued surrounding the NIH EST patent filings); Paul M. Rowe, *Patenting Genes*, J. CRAIG VENTOR and the *Human Genome Project*, 1 MOLECULAR MED. TODAY 12, 13 (1995) and Smith & Kettelberger, *supra* note 4, at 46-51 (discussing the debate regarding ESTs surrounding NIH's initial filings).

7. See sources cited *supra* note 6 (discussing the debate concerning whether ESTs are patentable).

8. See, e.g., Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 13-50 (1995) (detailing the prosecution history of the NIH EST patent applications).

9. *Genetics and the Law*, *supra* note 6, at 558-59; Eliot Marshall, *Patent Office Faces 90-Year Backlog; Patent Applications for DNA Sequences*, 272

These patent applications have been pending for a considerable period of time at the United States Patent and Trademark Office (PTO), in part, because the PTO is overwhelmed by the number of sequences in these applications, and until recently, was unsure about the patentability of these DNA segments.<sup>10</sup>

Recently, the PTO announced that ESTs are patentable subject matter.<sup>11</sup> This announcement stimulated a renewed uproar in the international community of human genome researchers concerning the patenting of ESTs.<sup>12</sup> However, now that it appears imminent that the PTO will award patents to ESTs, the debate focuses on the scope of the claims the PTO should award in the patents.<sup>13</sup>

Hypothetically, one of the biotech companies involved in the EST debate was founded by a Bedford Falls opportunist, Mr. Potter, who founded Potter's Gene Bank, one of the first companies to focus on creating a proprietary EST database.<sup>14</sup> Potter's Gene Bank randomly sequenced thousands of ESTs and applied for patents on all of them in hopes of controlling the fate of a major portion of the human genome.

Unfortunately, George Bailey's small biotech company, Bailey's ESTs and Genes (Bailey's), was slow in obtaining funding and failed to isolate its first EST until after Potter's Gene Bank isolated thousands. However, unlike Potter's Gene Bank, Bailey's focused on using ESTs to find genes and gene patterns that are

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SCIENCE 643, 643 (1996); Dan Goodin, *Gene Genie*, RECORDER, Aug. 20, 1997, at 1.

10. Bruce Lehman, *Major Biotech Issues for the U.S. Patent and Trademark Office*, 33 CAL. W. L. REV. 49, 59-60 (1996). See also Marshall, *supra* note 9, at 643-44 (discussing the huge backlog of patent applications claiming DNA sequences); James Coburn, *PTO Hearings on Nucleic Acid Sequences*, INTELL. PROP. TODAY, June 1996, at 15, 15 (discussing the large amount of resources necessary to examine pending "mega sequence" patent applications).

11. Dorothy Auth, *Are ESTs Patentable?*, 15 NATURE BIOTECH 911, 911 (1997); James Coburn, *EST's and Partial Sequences: Repercussions for the Biotech Client*, INTELL. PROP. TODAY, Aug. 1997, at 7; Vincent Kiernan, *Furore in US Over Patents for 'Bit part' DNA*, NEW SCIENTIST, Feb. 22, 1997, at 11. See also Goodin, *supra* note 9, at 1 (discussing the debate that followed the PTO announcement that ESTs are patentable subject matter).

12. See sources cited *supra* note 11 (discussing the concerns of the biotech community regarding EST patents).

13. See sources cited *supra* note 9 (discussing the concerns of the biotech community regarding the scope of EST patents).

14. See WONDERFUL LIFE, *supra* note 2. The author does not intend Mr. Potter's shrewd company to represent any of the actual biotech companies that focus on creating EST databases. However, there is a perception that some of the biotech companies involved with large scale EST discovery are attempting to obtain patents covering much more than their actual discoveries. Eisenberg, *supra* note 6, at 560-61; John Carey et al., *The Gene Kings*, BUS. WK., May 8, 1995, at 74.

correlated with human disease, and applied for patents only after a thorough characterization of the ESTs and genes. George Bailey has become increasingly concerned about the announcement that the PTO will award patents with broad claims for ESTs because he knows that Potter's Gene Bank filed patent applications on ESTs with broad claims. These broad claims cover Bailey's most promising discovery, the Uncle Billy gene, a candidate gene for the treatment of Alzheimer's disease.<sup>15</sup>

This Comment focuses on the appropriate protection the PTO should award for claims of patents that disclose ESTs and other uncharacterized, partial segments of the human genome. Part I provides a technical background relating to the human genome and ESTs. Part II focuses on patent laws and the application of these laws by courts to traditional inventions and to inventions related to the human genome. Part III relies on the hypothetical controversy in Bedford Falls and analyzes the effect of various scopes of intellectual property protection of ESTs on the development of efficacious medical products. In addition, Part III analyzes recent decisions by the Court of Appeals for the Federal Circuit (CAFC) involving patents on human genes and attempts to predict the scope of protection the CAFC will uphold for patents relating to ESTs and other fragments of the human genome. Based on this analysis, Part IV proposes minimum requirements that the PTO should adopt in granting patents to DNA segments derived from the human genome, such as ESTs, and suggests that the PTO should award a narrow scope of protection for these segments. Part IV then recommends that Congress, the PTO, and the biotech community consider implementing a new patent category for uncharacterized human DNA segments, such as ESTs, with a reduced term and a diminished examination process.

## I. THE HUMAN GENOME, GENES AND ESTS

The human genome is the entire set of DNA found in virtually every cell of the human body.<sup>16</sup> The human genome is organized into a series of chromosomes, each of which is composed of one continuous molecule of DNA that is arranged into interconnected functional segments of DNA.<sup>17</sup> The DNA of a segment consists of a sequential arrangement (called a DNA sequence) of four nucleotides of unspecified length and function.<sup>18</sup>

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15. See *WONDERFUL LIFE*, *supra* note 2 (involving the forgetful fictional character, Uncle Billy).

16. BENJAMIN LEWIN, *GENES* V 657 (Oxford Univ.) (1994).

17. *Id.* Human genome segments that are not genes provide a variety of functions. *Id.* at 749. For example, some segments are believed to be important for the structural integrity of the chromosome. *Id.* at 751-52.

18. *Id.* at 87. The four types of nucleotides in DNA are adenosine,

A small proportion of the DNA segments found on chromosomes, called genes, contain nucleotide sequences that have the capacity to direct the synthesis of proteins with specific amino acid sequences using enzymes found within the cell through a ribonucleic acid (RNA) intermediate.<sup>19</sup> Proteins carry out most of the processes of a cell.<sup>20</sup> Since only a specific subset of the genes in the human genome is expressed by a particular cell, cells of the body are capable of very specialized functions.<sup>21</sup> Scientists use modern techniques making it possible to work backward and direct the synthesis of DNA from an RNA molecule.<sup>22</sup> A DNA segment synthesized in this manner is called a complimentary DNA (cDNA).<sup>23</sup>

In the mid 1980s, the U.S. government, joined by other governments around the world, organized an international project, called the Human Genome Project, with the goal of sequencing all three billion nucleotides of the human genome.<sup>24</sup> Separate from the Human Genome Project, scientists in industry and academia analyzed the human genome by focusing on specific DNA segments derived from the human genome, such as expressed genes, in order to more quickly discover those genes likely to have clinical or commercial utility.<sup>25</sup>

In 1991, Craig Venter of the NIH utilized a non-traditional approach to rapidly obtain large amounts of meaningful information concerning the human genome.<sup>26</sup> His method focused on obtaining partial nucleotide sequence information from

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guanidine, thymidine, and cytidine. *Id.* Several CAFC opinions include background information regarding recombinant DNA technology. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1203 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991); *In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988).

19. See LEWIN, *supra* note 16, at 163-64. RNA is similar in structure to DNA in that it is a sequentially arranged segment of one of four nucleotides. *Id.* at 87. However, RNA is composed of the nucleotide uridine instead of the nucleotide thymidine, which is found in DNA. *Id.* Furthermore, RNA exists as a single-strand of nucleic acid, unlike DNA, which exists in a double stranded helical arrangement. *Id.* at 109, 163-64.

20. *Id.*

21. *Id.* at 163-64.

22. *Id.* at 641.

23. *Id.*

24. See sources cited *supra* note 3 (discussing the human genome project). Today, scientists have begun the final phase of that project, the actual sequencing of the DNA. Rowen et al., *supra* note 4, at 607.

25. See, e.g., Mark D. Adams et al., *Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project*, 252 SCIENCE 1651, 1651 (1991) (describing the general technique for isolating ESTs by utilizing RNA of expressed genes).

26. *Id.* at 1652-56.

cDNAs.<sup>27</sup> He called these partial nucleotide sequences "expressed sequence tags" or "ESTs."<sup>28</sup>

Although ESTs *per se* do not define functional genes or proteins, they are useful because they provide information regarding functional, full-length genes and they are a powerful tool for isolating these genes.<sup>29</sup> For example, although ESTs are quickly discovered using routine methods capable of being carried out almost exclusively using robotics, ESTs provide structural information regarding human genes, probes for discovering complete genes, and markers for specific locations on the human genome.<sup>30</sup> Furthermore, ESTs provide an opportunity for rapidly and inexpensively determining the extent to which a gene is expressed in a given cell type or tissue.<sup>31</sup>

Despite these utilities, ESTs have several inherent limitations.<sup>32</sup> For example, in most cases they do not provide the complete sequence of a cDNA.<sup>33</sup> Therefore, since many genes are composed in part of related or identical segments of DNA, a scientist sometimes cannot unequivocally determine the gene from which an EST is derived without further analysis.<sup>34</sup> Furthermore, ESTs are limited by the fact that methods employed to obtain rapid sequence determinations are less accurate than the more

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27. *Id.* at 1652.

28. *Id.* at 1651.

29. *See, e.g., id.* at 1655 (exemplifying the utility of ESTs in quickly providing some structural information regarding genes and chromosomes).

30. *Id.* at 1652-56. *See also* Mark D. Adams et al., *Rapid cDNA sequencing (expressed sequence tags) from a directionally cloned human infant brain cDNA library*, 4 NATURE GENETICS 373 (1993) (exemplifying the use of ESTs to obtain structural information regarding a gene and for identifying complete genes); W. Guo et al., *Genomic scanning for expressed sequences in Xp21 identifies the glycerol kinase gene*, 4 NATURE GENETICS 367 (1993) (exemplifying the use of ESTs to obtain structural information regarding a gene, and for identifying complete genes); Nickolas Papadopoulos et al., *Mutation of a 'mutL' homolog in hereditary colon cancer*, 263 SCIENCE 1625 (1994) (exemplifying the use of ESTs to discover full-length genes); MH Polymeropoulos et al., *Chromosomal distribution of 320 genes from a brain cDNA library*, 4 NATURE GENETICS 381 (1993) (exemplifying the use of ESTs as markers for specific chromosomal locations).

31. Adams et al., *supra* note 25, at 1562-66 (identifying ESTs expressed in the human brain).

32. *See, e.g., id.* (exemplifying that ESTs usually do not encompass entire genes and do not provide any useful information and have a decreased accuracy of DNA sequence determination); Leslie Roberts, *Gambling on a Shortcut to Genome Sequencing*, 252 SCIENCE 1618, 1619 (1991) (discussing limitations of ESTs related to the inability to discover all expressed genes by ESTs and the inability of ESTs to provide information related to expression control regions of genes).

33. *E.g., Adams et al., supra* note 25, at 1652-54.

34. Roberts, *supra* note 32, at 1618.

careful and typical sequencing methods.<sup>35</sup> Finally, the routine methods employed in discovering ESTs, although extremely efficient, eliminate some of the creativity and inventiveness traditionally employed in gene discovery.<sup>36</sup>

Following the initial discovery of ESTs by Craig Venter, other researchers and biotech companies discovered very large numbers of ESTs and further developed EST technologies.<sup>37</sup> Several biotech companies generate considerable revenue by licensing access to their vast EST databases, which they protect as trade secrets, to large pharmaceutical and diagnostics companies.<sup>38</sup> In addition, several large public EST databases were established, in part, as a result of corporate funding.<sup>39</sup> At least one of these databases

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35. Mark S. Boguski & Gregory D. Schuler, *ESTablishing a Human Transcript Map*, 10 *NATURE GENETICS* 369, 371 (1995). Typically, sequencing is done across both strands of a DNA segment using overlapping DNA segments in order to allow a scientist to manually resolve redundancies that arise. Rowen et al., *supra* note 4, at 607. Craig Venter's group in their initial study of ESTs determined the average DNA sequence accuracy for ESTs less than four hundred base pairs in length to be 97.7%. Adams et al., *supra* note 25, at 1655. However, a more recent report, possibly based on improved methods for EST determinations, suggests that the accuracy of DNA sequence determinations for ESTs is 99%. Rowe, *supra* note 6, at 13. Even this level of accuracy is far lower than the 99.9% accuracy required for DNA sequences submitted as part of the human genome project. Rowen et al., *supra* note 4, at 607.

36. See Eisenberg & Merges, *supra* note 8, at 33 (discussing obviousness of using the sequencing method utilized in the original EST publication to discover other ESTs); Kiernan, *supra* note 11, at 11 (quoting renowned molecular biologist Leroy Hood, "ESTs are the ultimate in non-thinking"); Roberts, *supra* note 32, at 1618 (quoting Craig Venter describing ESTs as the "ultimate in simplicity").

37. See sources cited *supra* note 9 (discussing EST initiatives by biotech companies). Incyte Pharmaceuticals and Human Genome Sciences (HGS) have filed patent applications apparently covering hundreds of thousands of ESTs. *Genetics and the Law*, *supra* note 6, at 563; Goodin, *supra* note 9, at 1. Incyte's database reportedly now contains 2.5 million ESTs representing approximately 100,000 distinct human genes. *Incyte Pharmaceuticals Home Page, LifSeq® database description* (visited Apr. 4, 1998) <<http://www.incyte.com/products/lifseq.html>> [hereinafter *LifSeq*].

38. *Genetics and the Law*, *supra* note 6, at 566-69.

39. *Id.* at 569-71 (describing Merck/Washington University EST initiative); *dbest: Database of Expressed Sequence Tags* (visited Apr. 4, 1998) <<http://www.ncbi.nlm.nih.gov/dbEST>> (containing EST sequences entered into the public nucleotide sequence database Genbank, including those generated by the Washington University program); *UniGene* (visited Apr. 4, 1998) <<http://www.ncbi.nlm.nih.gov/schuler/unigene>> (containing the National Center for Bioinformatics EST database of transcript maps); *Washington University Merck & Co. EST Project Home Page* (visited Apr. 4, 1998) <<http://genome.wustl.edu/est/esthmpg.html>> [hereinafter *Washington University EST Project Home Page*] (containing information regarding Washington University EST discovery program, partly funded by Merck & Co.).



provides ESTs in pairs representing the ends of cDNAs, rather than as individual ESTs arising from within a cDNA.<sup>40</sup> Certain databases are "functional" in that they provide more than structural information regarding ESTs because they contain huge amounts of data regarding relative expression patterns of particular ESTs in various tissues, developmental states, and diseases.<sup>41</sup> Furthermore, scientists can utilize information in EST databases as a first step in the discovery of single nucleotide polymorphisms (SNPs).<sup>42</sup> Single nucleotide polymorphisms are single base pair differences that occur in the same chromosomal location between different people that reveal differences between larger segments of the genomes of these people.<sup>43</sup>

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40. See Boguski & Schuler, *supra* note 35, at 370 (indicating that the 3' and 5' ends of approximately 200,000 human cDNAs have been sequenced); *Washington University EST Project Home Page*, *supra* note 39 (indicating in a disclaimer that every effort was made to sequence both ends of the cDNA clones).

41. See, e.g., *LifSeq*, *supra* note 37 (containing EST expression informations from many different cells and tissues in normal and diseased tissue); *The Bodymap Anatomical Expression Database* (visited Apr. 8, 1998) <<http://www.imcb.osaka-u.ac.jp/bodymap>> (containing data regarding gene expression in various tissues). Several articles have been published which have identified target genes by comparing EST information. M. A. Watson & T. P. Flemming, *Isolation of Differentially Expressed Sequence Tags from Human Breast Cancer*, 54 *CANCER RES.* 4598, 4598 (1994); Vasmatazis et al., *Discovery of three genes specifically expressed in human prostate by expressed sequence tag database analysis*, 95 *PROC. NAT'L ACAD. SCI. U.S.A.* 300, 300 (1998). Several techniques have been developed which utilize ESTs to analyze gene expression and find target genes. Philip Hieter & Mark Boguski, *Functional Genomics: It's All How You Read It*, 278 *SCIENCE* 601, 601 (1997); Tom Strachan et al., *A New Dimension for the Human Genome Project: Towards Comprehensive Expression Maps*, 16 *NATURE GENETICS* 126, 126 (1997).

42. NCBI News, *Unigene Collection*, Aug. 1996 (visited Apr. 11, 1998) <[NCBI/Web/newstlr/Aug96.html](http://NCBI/Web/newstlr/Aug96.html)>. The Unigene database can be used to find polymorphisms by combining the data from many ESTs that appear to have been generated from different cDNAs derived from the same gene. *Id.*

43. Francis S. Collins et al., *Variations on a Theme: Cataloging Human DNA Sequence Variation*, 278 *SCIENCE* 1580, 1580-81 (1997). Single nucleotide polymorphisms act as markers for larger stretches of DNA, such as specific alleles of a gene. *Id.* The capability of scientists to discover large numbers of SNPs quickly and affordably provides information for new proprietary databases and makes possible pharmacogenomic studies analyzing the correlation of a person's specific genome to a drug response. Aris Persidis, *The Business of Pharmacogenomics*, 16 *NATURE BIOTECH* 209, 209-10 (1998). Spurred by a pharmacogenomic-related alliance of two companies based on a large SNP database, scientists and biotech patent experts currently debate whether SNPs should be patented. Elliot Marshall, *Snipping Away at Genome Patenting*, 277 *SCIENCE* 1752, 1752 (1997).

## II. PATENT LAW AND ITS APPLICATION TO HUMAN GENES

### A. *The Quid Pro Quo of Patent Law*

Our founding fathers recognized that advancement of technology could be accelerated if the government granted inventors the exclusive right to their inventions for a limited period of time.<sup>44</sup> As a result, Congress enacted a series of laws that establish a *quid pro quo* between an inventor and the rest of society.<sup>45</sup> This *quid pro quo* gives an inventor the right to exclude others from making, selling, or using his invention for a limited period of time, while giving society a clear disclosure of the invention.<sup>46</sup> The intent is to promote the development of technology by rewarding an inventor for his invention, while providing society a disclosure of his invention which can be further developed into other patentable inventions.<sup>47</sup> Courts and the PTO must uphold this purpose whenever they apply the patent laws to a new discipline such as human genome research.<sup>48</sup>

### B. *Recent Changes to U.S. Patent Laws*

Congress recently changed U.S. patent laws, including those relating to patent terms and the types of patent applications available to inventors, in order to make U.S. patent law more consistent with patent laws in other countries.<sup>49</sup> For example, U.S. Provisional patent applications are now available which do not undergo an examination by the PTO, have a decreased cost, and expire after one year.<sup>50</sup> However, the U.S. patent system does not contain a "diminished" type of patent that, unlike a provisional application, issues as a patent but is reduced in term and

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44. U.S. CONST. art. I, § 8, cl. 8. See DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, at overview 1-15 (1995) (describing the historical development of patent law).

45. CHISUM, *supra* note 44, at 1-15.

46. *Id.*

47. *Id.*

48. See Adler, *supra* note 6, at 909 (discussing how biotech patent law is being developed based on the established application of patent law to the chemical arts); Rebecca S. Eisenberg, *Structure and Function in Gene Patenting*, 15 NATURE GENETICS 125, 125 (1997) [hereinafter *Structure and Function in Gene Patenting*] (discussing how patent law resolves new controversies).

49. 35 U.S.C. § 111 (1995); 35 U.S.C. § 154 (1998); 37 C.F.R. § 1.9 (1997).

50. 35 U.S.C. § 111 (1995); 37 C.F.R. § 1.9 (1997); 37 C.F.R. § 1.16 (1997); CHISUM, *supra* note 44, § 11.02[1]. The filing date of these applications can be used as the filing date of a nonprovisional application if the nonprovisional application is filed within 12 months of the filing of the provisional application. *Id.*

examination compared to a utility patent.<sup>51</sup> This "diminished" type of patent is available in other countries such as Australia.<sup>52</sup>

### C. The Scope of Patent Protection for ESTs

#### 1. The Current Debate

The requirements for obtaining a patent for an invention can be divided as follows: (i) determining whether the discovery falls within one of the statutory categories; (ii) determining whether the discovery has utility and possesses the level of novelty and nonobviousness to justify being an invention; and (iii) determining the form and level of disclosure needed to receive a patent.<sup>53</sup> In the past, various individuals and organizations interested in biotech debated whether ESTs were patentable inventions, especially when considering the utility requirement.<sup>54</sup> Now that it appears the PTO will award such patents, these same individuals and organizations debate the limitations that the written-description requirement found in 35 U.S.C. § 112 places on the scope of the claims of these patents.<sup>55</sup> The scope of the claims is important because it determines, for example, whether an inventor can exclude others from making or selling an entire protein-coding DNA segment or gene that contains a patented EST.<sup>56</sup> The entire

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51. Patents Act, 1990, § 52 (Austl.). The Australian petty patent has a six year rather than 20 year term, involves a narrower prior art base, and involves an accelerated examination. *Id.* In addition, the newly proposed 'Innovation' patent as a replacement for the current petty patent which would provide accelerated patent protection for a reduced term at a lower cost for inventions which meet a lowered innovation threshold. *Australia to Consider Second-Tier 'Innovation' Patent*, 9 J. PROPRIETARY RTS. 28, 28 (1997).

52. See *supra* note 51 and accompanying text for a discussion of the Australian petty patent and proposed Innovation patent.

53. See 35 U.S.C. § 101 (1975) (providing utility requirement and patentable subject matter categories); 35 U.S.C. §102 (1975) (providing novelty requirement); 35 U.S.C. § 103 (1975) (providing nonobvious subject matter requirement); 35 U.S.C. § 112 (1975) (providing requirements of the specification of the patent application including the best mode, enablement, and written-description requirements, as well as the requirement for a claim "particularly pointing out and distinctly claiming" the invention).

54. See sources cited *supra* note 6 (discussing the early debate which focused on whether ESTs meet the utility requirement).

55. Auth, *supra* note 11, at 911-12; Goodin, *supra* note 9, at 2-3; Eisenberg & Merges, *supra* note 8, at 37-51; Lynn Pasahow & Andrew Kumamoto, *Human Genome Project Raises Patenting Issues*, NAT'L L. J., Oct. 20, 1997, at C31, C32; Benjamin Thorner, *Trading Patent Rights for Research Tools: What's at Stake?*, 15 NATURE BIOTECH 1024, 1025-26 (1997); Gail Dutton, *Genomic Intellectual Property, Patent Claims are Narrowing Based on Genomic Data*, GENETIC ENGINEERING NEWS, Feb. 15, 1998, at 20.

56. See sources cited *supra* note 55 (discussing the effects of a broad scope of patent protection for EST patent disclosures). In addition, the written-

protein-coding region is much more likely to be clinically useful than the EST itself.<sup>57</sup>

## 2. *The Written-Description Requirement*

The written-description requirement assures those skilled in the art that the applicant was in full possession of the invention at the time of filing the application.<sup>58</sup> The requirement also functions to assure the *quid pro quo* of patent law, namely, the availability of the disclosure enables others to develop improvements on the invention and to practice the invention after the patent expires.<sup>59</sup>

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description requirement mandates that a patent application contain an enabling disclosure, at least one claim "particularly pointing out and distinctly claiming" the invention, and reveal the best mode of carrying out the invention. 35 U.S.C. § 112 (1975). Because of the overlapping nature of the enablement, written-description, and "precise claim" requirements, courts sometimes confuse these requirements. See CHISUM, *supra* note 44, § 8.03[2]. In fact, Justice Markey argues that the written-description requirement should not be a separate requirement because it is redundant and confusing. *In re Barker*, 559 F.2d 588, 594-95 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064, (1978) (Markey, J., dissenting); CHISUM, *supra* note 44, § 7.04[1][a][iv]. The importance of these requirements is as follows: they define the scope of protection against potential infringing parties, provide boundaries within which other inventors cannot obtain patents, and establish that the applicant is entitled to this scope of protection. *Id.* These requirements also address many of the concerns that individuals and groups with interests in biotech raise with respect to granting patents to ESTs. See *supra* note 55 for articles that discuss these requirements in the context of EST patent applications.

The specification of a patent application must contain at least one claim "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 (1975). The claims define the scope of the invention; their purpose is in determining whether the invention meets the requirements for patentability, and in determining infringement. CHISUM, *supra* note 44, § 8.01. The transitional phrases "comprising," "consisting of," and "consisting essentially of" have very different and important meanings regarding the scope of patent claims. U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2111.03 (6th ed. 1996) [hereinafter M.P.E.P.]. The transition phrase "consisting of" excludes any element or step not listed in the claim. *Id.* The phrase "consisting essentially of" limits the claim to the listed elements or steps "and those that do not *materially* affect the *basic* and *novel* characteristics of the claimed invention." *Id.* (emphasis in original). The term "comprising" is open-ended and does not exclude additional elements or steps. *Id.* Therefore, a patent claim which reads "A DNA fragment comprising the nucleotide sequence GGCGG" would include any DNA sequence, including a 2000bp DNA sequence encoding a complete protein, which includes the sequence GGCGG at some point in the sequence. Auth, *supra* note 11, at 911.

57. See sources cited *supra* note 55 (discussing the effects of a broad scope of patent protection for EST patent disclosures).

58. CHISUM, *supra* note 44, § 7.04; *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

59. *Id.*

The CAFC follows the precedent set by its predecessor, the Court of Customs and Patent Appeals (CCPA), in holding that to meet the written-description requirement an inventor must precisely describe an invention by "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."<sup>60</sup>

### 3. The Written-Description Requirement and DNA Segments

Recent CAFC decisions indicate that in order to meet the written-description requirement for a claim to a gene, a specification must recite the complete nucleotide sequence of that gene.<sup>61</sup> In *Fiers v. Revel*, the CAFC held that a DNA encoding beta-interferon was not adequately described by a patent unless the patent disclosed the entire nucleotide sequence of that DNA.<sup>62</sup> The CAFC held that disclosure of a method for isolating a fragment encoding beta-interferon did not meet the written-description requirement for a DNA encoding beta-interferon.<sup>63</sup> In reaching its decision, the CAFC opined that to meet the written-

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60. *Lockwood*, 107 F.3d 1565, 1572. In *Lockwood*, the Court held that a computer entry system was not described by an earlier application which failed to disclose some of the limitations of the later filed application. *Id.* In *Ruschig v.*, an inventor sought to add a claim to a certain species of a chemical compound during prosecution of a patent application. 379 F.2d 990, 991 (C.C.P.A. 1967). The original patent application described reagents necessary to prepare the species and claimed a genus encompassing this chemical species. *Id.* However, in affirming the PTO Board of Appeals (Board) rejection of the species claim, the CCPA held that the claim to the species was not allowable because the specification did not disclose the compound as something the inventor invented. *Id.* at 995. See also CHISUM, *supra* note 44, § 7.04 (discussing the written description requirement). In its opinion the court stated that:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared-or have not yet been made, which is more like the case here—to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

*Ruschig*, 379 F.2d at 994-95.

However, the CAFC holds that where a patent contains claims to a genus, every species that falls within the genus need not be described in the patent. *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988). In *Utter*, the CAFC held that a patent disclosure had a sufficient written description for a genus, even though the claim covered some species that were patentably distinct from the generic claim. *Id.* The patent applications in this interference were for scroll compressors for air conditioners. *Id.* One species of the genera contained an external pivot, which was not described in the patent for the genera. *Id.*

61. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1567 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993).

62. *Fiers*, 984 F.2d at 1170.

63. *Id.* at 1169-71.

description requirement, a DNA sequence must be defined precisely "such as by structure, formula, chemical name, or physical properties."<sup>64</sup>

Recently, in *Regents of the University of California v. Eli Lilly*, the CAFC affirmed its position that the written description of a claimed DNA segment requires a recitation of the DNA sequence of the complete DNA segment.<sup>65</sup> In *Regents*, the CAFC found that the written-description requirement was not met for a claim to the human insulin cDNA, since the patent did not disclose the DNA sequence of that cDNA, even though the patent disclosed the amino acid sequence of human insulin.<sup>66</sup> The court reasoned that since a DNA segment is not obvious unless its sequence is determined, the DNA segment is not described unless its sequence is determined.<sup>67</sup> Thus, the CAFC requires the disclosure of a complete DNA sequence of a claimed DNA segment in order to meet the written-description requirement for that DNA segment.<sup>68</sup>

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64. *Id.* at 1171.

65. *Regents*, 119 F.3d at 1567.

66. *Id.* The patent disclosed the DNA sequence of the rat homologue and the amino acid sequence of the human protein. *Id.* at 1562. The court also held that the disclosure did not provide a sufficient written description for generic claims to vertebrate and mammalian insulin cDNAs since it revealed the structure of only one species. *Id.* at 1567-69.

67. *Id.* at 1567.

68. Another important requirement of biotech patent applications in addition to the written-description requirement is the enablement requirement. 35 U.S.C. § 112 (1975). To meet the enablement requirement, a patent disclosure must teach one of ordinary skill in the art how to make and use the invention. CHISUM, *supra* note 44, § 7.01. The essential question is whether the scope of enablement is as broad as the scope of the claims. *Id.* § 7.03 [7]. However, a patent may be enabled even though some experimentation is necessary. *In re Wands*, 858 F.2d 731, 737-38 (Fed. Cir. 1988). In *Wands*, the court provided several factors that are relevant in determining whether undue experimentation is required. *Id.* at 731. These factors include:

- (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.

*Id.* The court analyzed these factors and held that it would not require undue experimentation for one of ordinary skill in the art to make the claimed antibodies. *Id.* at 740. In claims to generic compounds, an inventor need not disclose every species to meet the enablement requirement for the generic compounds. CHISUM, *supra* note 44, at 7.03 [4]. Rather, a patent must disclose a representative number of species within the genus. *Id.* In *Application of Angstadt*, the court held that even in an unpredictable art applicants do not have to disclose every species encompassed by their claims. 537 F.2d 498, 502-03 (C.C.P.A. 1976). Furthermore, courts hold that the mention of representative compounds for generic claims may substitute for an explicit description of generic claim language. *In re Robins*, 429 F.2d 452, 456-

### III. WHAT IS THE IDEAL SCOPE OF PATENT PROTECTION FOR ESTS?

This Part attempts to identify the ideal intellectual property protection for ESTs and other DNA segments isolated from the human genome. Section A considers the scope of protection that it appears the PTO will award for EST patent claims and considers the effects of a broad scope of protection on a hypothetical medical product discovery. Section B further analyzes this medical product discovery in order to define the objectives for an optimal scope of protection for EST patents. Section C compares various intellectual property protection options for ESTs to determine the best option. Section D considers the scope of protection that the CAFC is likely to uphold and compares this to the ideal scope of protection from a medical product development perspective. Section E considers the written-description requirement, taking into consideration several factual variables surrounding EST

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57 (C.C.P.A. 1970).

The CAFC has also addressed the enablement requirement with respect to biotech inventions. *Genentech, Inc. v. Novo Nordisk A/S, Novo Nordisk or North America, Inc., and Novo Nordisk Pharmaceuticals, Inc.*, 108 F.3d, 1361, 1363-68 (Fed. Cir. 1997); *In re Deul*, 51 F.3d 1552, 1556 (Fed. Cir. 1995); *Amgen, Inc. v. Chugai Pharmaceuticals Co., Ltd. and Genetics Institute, Inc.*, 927 F.2d 1200, 1212-14 (Fed. Cir. 1991). The CAFC requires that a patent contains an extensive characterization of a gene to enable broad claims encompassing that gene and variants with similar properties. *Amgen*, 927 F.2d at 1213-14. See also Kenneth Chahine, *Going Beyond the Native: Protecting DNA and Protein Patents*, 15 NATURE BIOTECH 183, 185 (1997) (discussing the characterizations of a gene necessary to cover broad patent claims encompassing variants of that gene). The CAFC has invalidated several early patents to recombinant DNA discoveries that contained broad claim language. *Amgen*, 927 F.2d at 1213-14; *Genentech*, 108 F.3d at 1366-68. For example, in *Amgen* the CAFC held that a claim to every possible analog of the human erythropoietin gene that encoded the erythropoietin protein was not enabled by a disclosure that provided data from several analogs of the gene. 927 F.2d at 1213-14. The Court held that a method for making more of the specific analogs and structural requirements for the compounds with EPO-like activity was required. *Id.*

More recently, in *Genentech*, the CAFC held that a patent which disclosed the DNA sequence of mature human growth hormone was not enabled for the production of this protein through a fusion protein intermediary. 108 F.3d at 1366-68. The CAFC held that the patent specification did not enable the production of mature growth hormone in this manner because this method of production was only generally described in the specification, and the technique had never successfully been used before the patent application was filed. *Id.* at 1366.

In *Deuel*, the CAFC again indicated its reluctance to award broad claims to recombinant DNA molecules. 51 F.3d at 1559. In this case, the court questioned whether a patent was enabled where the claims were directed to all of the nucleotide sequences that code for the native amino acid sequence of the HBGF proteins, but the patent disclosed only the native sequence. *Id.* at 1560.

discoveries. Section F considers whether the written-description requirement is met for an EST DNA segment itself, considering several technical limitations of ESTs. Finally, Section G considers the optimal scope of protection for other inventions derived from the human genome.

*A. The PTO's Intent to Award ESTs a Broad Scope of Patent Protection and the Effect of this Broad Scope on a Hypothetical Medical Product Discovery*

In recent scientific meetings, officials at the PTO indicated that patent protection that, in effect, encompasses an entire cDNA based on the disclosure of an EST, can be granted.<sup>69</sup> To determine the effect on medical breakthroughs of providing such broad patent protection to ESTs, and to set objectives for optimal patent protection of ESTs, consideration is given to a hypothetical series of discoveries, starting with the discovery of an EST and culminating in a medical breakthrough.<sup>70</sup>

We start by analyzing the key milestones in the isolation and development of the Uncle Billy gene.<sup>71</sup> First, Potter's Gene Bank embarks on a large-scale EST discovery project by sequencing thousands of ESTs.<sup>72</sup> The company applies for broad patent protection on the ESTs even though the only known information regarding the ESTs, besides their nucleotide sequence, is their

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69. See *supra* note 55 and accompanying text (discussing the announcement by the PTO that patents to ESTs will be awarded). From the comments of PTO officials, it appears that the PTO will allow claims that incorporate "comprising" language in patents which disclose ESTs. *Id.* See *supra* note 56 for a discussion of the meaning of various claim terms. The comments of PTO officials indicate that an acceptable claim in a patent containing an EST disclosure might read: "A segment of DNA comprising the sequence..." followed by the sequence of the EST. Auth, *supra* note 11, at 911-12; Pasahow & Kumamoto, *supra* note 55, at C31. The patent protection against infringement for a claim with this verbiage covers any DNA sequence, including the full-length gene, which contains the EST sequence. See *supra* notes 55-56 for articles and accompanying text discussing the scope of protection provided by DNA segment claims with "comprising" language.

70. Many of the discoveries in this hypothetical series are based on actual discoveries. These actual discoveries are referenced in the footnotes associated with the description of the hypothetical discoveries in the text.

71. See *supra* note 15 and accompanying text for a reference describing the "Uncle Billy" gene.

72. See *supra* notes 37 and 39 and accompanying text for a discussion of private and public organizations that have embarked on large-scale EST discovery projects. In the hypothetical discovery scenario, Potter's database contains ESTs derived from cDNA libraries from a variety of organs, individuals, and disease states. See *supra* note 41 and accompanying text for a discussion of functional databases and the use of ESTs to discover target genes.



tissue of origin.<sup>73</sup> Unknown to Potter's Gene Bank at the time of filing their EST patent applications, one of the ESTs, CO292, contains the sequence of a small segment of the Uncle Billy gene.<sup>74</sup>

Second, Potter's Gene Bank enters into a lucrative licensing agreement with Big Pharma Healthcare Inc. (Big Pharma). Potter's Gene Bank grants Big Pharma access to its functional EST database to identify candidate genes for cancer treatments and diagnostics.<sup>75</sup>

Third, Bailey's identifies two overlapping ESTs, BFHS3 and BFHS1928, which together reveal the sequence of the entire protein-coding region of the human Uncle Billy gene.<sup>76</sup> Based on a comparison of the expression of these ESTs in normal and Alzheimer's disease-affected brains, Bailey's learns that the Uncle Billy gene is expressed in the normal brain but not in the brains of Alzheimer's patients.<sup>77</sup> Based on an extensive characterization of the Uncle Billy gene in many mammalian species, including humans, Bailey's files a patent application claiming all mammalian Uncle Billy genes, and subsequently is awarded a patent with this broad claim scope.<sup>78</sup>

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73. See *supra* notes 5 and 9 and accompanying text for references and a discussion of the large numbers of EST patent application filings, first from the public and then from the private sector.

74. See Eisenberg, *supra* note 48, at 127-29 (discussing the discovery of the leptin receptor, and the current dispute regarding patent rights to the gene encoding that receptor, in light of the presence of another patent application to the gene encoding a previously unknown isoform of that receptor, an EST in the public domain containing part of the DNA encoding the receptor and the likelihood of a patent application filed by a private company covering the leptin receptor based on an EST disclosure); Judy Foreman, *Research Teams Race to Air Discovery of Gene Tied to Cancer*, BOSTON GLOBE, Mar. 28, 1997, at A11 (discussing the discovery of a new gene, P-TEN or MMAC1, by separate groups who are each seeking patents). There is a possibility that a biotech company has already applied for a patent on that gene using information from ESTs. *Id.*

75. See *supra* note 38 and accompanying text for a discussion of the licensing agreements that have been entered into between biotech companies and large pharmaceutical companies for access to EST databases.

76. See *Unigene*, *supra* note 39 (indicating that some of the ESTs from public databases overlap to yield an entire cDNA sequence); *Lifseq*, *supra* note 37 (indicating in *LifseqFL* contains full length gene sequences which are generated by assembling, *inter alia*, EST sequences).

77. See *supra* note 30 and accompanying text for a discussion of the use of EST databases to discover target genes for specific diseases.

78. See also *Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1567-69 (Fed. Cir. 1997) (discussing patent claims which attempted to cover all vertebrate or all mammalian insulin cDNAs). In *Regents*, the court broadly defined a type of characterization that would meet the written-description requirement for an entire genus:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide

Fourth, publication of the Uncle Billy gene sequence follows the issuance of the U.S. patent. This allows Mr. Gower, a researcher at New York University, to make a key discovery that improves the efficacy of all forms of gene therapy.<sup>79</sup>

Fifth, encouraged by the findings of Bailey's, Sam Wainwright's Fortune 500 company Hee Haw Healthcare Inc. (Hee Haw) signs a licensing agreement with Bailey's for the use of the Uncle Billy gene for the treatment of Alzheimer's.<sup>80</sup> Hee Haw also signs a licensing agreement with Mr. Gower for rights to use his gene therapy discovery with the Uncle Billy gene.

Finally, Hee Haw licenses the rights to many other genes from several other biotech companies for use on a diagnostic gene chip.<sup>81</sup> This chip reveals the gene expression pattern of those patients who will respond to gene therapy using the Uncle Billy gene.<sup>82</sup>

Soon after Hee Haw obtains encouraging results from clinical trials using the Uncle Billy gene in combination with the diagnostic gene chip, the PTO issues a patent to Potter's Gene Bank for their CO292 EST with broad claims that encompass the entire Uncle Billy gene.<sup>83</sup> Distraught, George Bailey heads for a bridge.

### *B. Objectives for Optimal Protection of ESTs*

The most obvious observation from this hypothetical discovery series is the danger of awarding overly broad patents based on EST disclosures. This scenario illustrates that broad

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sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

*Id.* at 1569.

79. See WONDERFUL LIFE, *supra* note 2 (casting the apparent alcoholic pharmacist Mr. Gower). Currently, in the United States, when patents are issued the entire patent file, including the patent specification is open to the public. 37 C.F.R. § 1.11 (1997). Furthermore, inventors can publish their discoveries up to 1 year before filing an application and still retain their patent rights on the discovery. 35 U.S.C. § 102 (1975).

80. See, e.g., *Structure and Function in Gene Patenting*, *supra* note 48, at 128 (discussing a similar agreement, reportedly worth \$500,000, for developing commercial products from a patented gene and its protein product).

81. See Marshall, *supra* note 43, at 1753 (discussing "poly 2000 chip" a diagnostic medical tool of the future); Strachan et al., *supra* note 41, at 126-27 (discussing gene "chip" technologies, which allow the analysis of the expression of thousands of genes simultaneously).

82. See *supra* note 81 and accompanying text for articles discussing gene chips.

83. See *supra* note 55 and accompanying text for a discussion of the broad scope of patent protection that the PTO appears prepared to award based on EST disclosures.

patents based on EST disclosures provide extensive control to companies who merely determine the sequence of a small DNA fragment in a routine mass-sequencing procedure while disclosing little about the true nature, function, or utilization of the associated gene. Such companies get the power to control the development of the EST into a medical breakthrough without significantly contributing to the achievement.

Another important observation this scenario reveals is that the greatest value of ESTs may not lie in the individual ESTs, but may lie in the synergism of EST data in functional EST databases.<sup>84</sup> Optimally then, patent protection awarded for ESTs must promote the construction and expansion of EST databases.<sup>85</sup>

The hypothetical gene discovery scenario also reveals that it is likely that medical breakthroughs which utilize human genome discoveries, such as the Uncle Billy gene, depend on many other technologies and discoveries. Therefore, it is likely that large healthcare companies, like Hee Haw, will have to wade through a complex web of intellectual property to license optimal technologies and ultimately market human genome discoveries.<sup>86</sup>

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84. See *supra* note 41 and accompanying text for a discussion of functional EST databases. Arguably the most important and difficult discovery from a scientific perspective in the determination and use of human genome information is the determination of which genes or gene combinations might be involved in disease progression from the huge number of genes and possible gene combinations. Carey et al., *supra* note 14, at 74. According to Michael Steinmetz, vice-president for clinical R&D at Hoffman-LaRoche, "Identifying genes is only the beginning of a long, painful, and expensive process of drug development." *Id.* Possibly the greatest value of ESTs is that they provide a relatively inexpensive and quick method for obtaining "snapshots" of gene expression patterns for a given cell or tissue. See *supra* note 41 and accompanying text for a discussion of functional EST databases. By comparing the pattern of gene expression from these "snapshots," candidate diagnostic and pharmaceutical genes and gene combinations are revealed. See generally Watson & Flemming, *supra* note 41, at 4598 (utilizing this strategy to identify a candidate gene involved in breast cancer). This is one reason that small genome companies have obtained large licensing agreements for access to their huge EST libraries which contain EST gene expression "snapshots" from many individuals for many tissue types and many disease states. *Lifseq*, *supra* note 37. Drug discovery companies have paid large sums of money for access to Incyte's databases. *Genetics and the Law*, *supra* note 6, at 568-69.

85. See *supra* notes 37, 39, and 41 and accompanying text for a discussion of EST databases. Potter's Gene Bank is not dependent on a broad scope of protection for its ESTs to generate revenue to continue to develop its massive database, since it is the power of Potter's EST database as a whole in revealing target genes that is most valuable to Big Pharma. *Genetics and the Law*, *supra* note 6, at 566-70.

86. See Marshall, *supra* note 43, at 1752 (discussing Merck's Reasons for opposing patenting genetic data). Merck's Vice President of Research Strategy Worldwide, Alan Williamson, comments that "Merck opposes patenting genetic data because it 'noticed that royalty claims were stacking up' on its

The royalty payments that result from such complex arrangements would eliminate the incentive for companies to proceed.<sup>87</sup> In addition, the intellectual property web provides many companies an opportunity to exclude patients from access to valuable medical breakthroughs.<sup>88</sup> Therefore, the ideal patent protection for patents to ESTs must seek to minimize the number of patents covering complex medical breakthroughs.

Finally, the hypothetical gene discovery scenario reveals the value in publication of EST sequences. Fundamental discoveries, such as that of Mr. Gower, that utilize the disclosed invention to improve an entire discipline, are critical to assure continuous technological development that promotes further medical breakthroughs.<sup>89</sup> Therefore, the ideal patent protection for patents to ESTs must provide public access to the sequences.<sup>90</sup>

### *C. The Effects of Various Forms of Patent Protection for ESTs*

Based on the objectives of patent protection for ESTs revealed above, the PTO must award patents based on EST disclosures with a limited scope of protection, not encompassing sequences outside the EST, to assure the best balance of these objectives. First, an EST patent of narrow scope would not allow the EST

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products." *Id.* See also Collins et al., *supra* note 43, at 1581 (discussing the discovery of large numbers of SNPs and indicating that "[a]lthough some of these private collections [of SNPs] may be 'publicly available,' a tangled web of restrictive intellectual property attachments might well arise, inhibiting many researchers from using these powerful tools.").

87. See *supra* note 86 and accompanying text for a discussion of the possible tangled web of intellectual property for genomic discoveries that could result in high royalty payments for companies that market medical products.

88. A patent grants an inventor the right to exclude others from making or selling his product. 35 U.S.C. § 154(a)(1) (1984). In many cases, owners of patent rights license the right to sell their invention to others for reasonable royalties because of the revenue provided. Thorner, *supra* note 55, at 1026.

89. See, e.g., Philip H. Abelson, *Science and Technology Policy; Editorial*, 267 *SCIENCE* 435 (1995) (giving an example of how a basic research discovery has profoundly effected biotech and has started to impact medical products); H. A. Ehrlich et al., *Recent Advances in the Polymerase Chain Reaction*, 252 *SCIENCE* 1643 (stating how polymerase chain reaction is used in the discovery of ESTs).

90. Publication of EST sequences will occur if patents are granted on these sequences because all patents are published. 37 C.F.R. § 1.11 (1997). Public access to EST sequences also occurs through public disclosure of those sequences. See *supra* note 39 for a discussion of public EST databases. When all of these observations concerning the discovery and development of human genomic information are considered, the optimal scenario for intellectual property protection of ESTs is one which promotes the establishment and expansion of EST libraries, promotes public disclosure of information to facilitate the development of new technologies, and minimizes the intellectual property web associated with medical breakthroughs.

claim to encompass a medical product based on an entire gene, thereby reducing the licensing burden on companies that market such products.<sup>91</sup> However, the patent protection would allow EST owners to prohibit others from making or using the EST.<sup>92</sup> Second, awarding patents on ESTs, unlike protecting them as trade secrets, discloses ESTs to the public where they can be freely used by basic researchers and licensed by private institutions.<sup>93</sup> Furthermore, to satisfy the best-mode requirement for EST specifications, inventors can reveal important information related to the EST, including tissue distribution and similarities to segments of known proteins.<sup>94</sup> Third, awarding patent protection to ESTs, unlike disclosing ESTs to the public without seeking patent protection, provides incentive to genomics companies to continue discovering ESTs by ensuring that a market for licensing access to EST databases exists.<sup>95</sup>

*D. The CAFC is Likely to Invalidate Broad Claims Based on EST Disclosures*

Based on recent precedent, the CAFC is likely to invalidate broad claims based on EST disclosures in view of the written-description requirement.<sup>96</sup> In *Regents of the University of California v. Eli Lilly* and *Fiers v. Revel*, the CAFC held that the patent must disclose the DNA sequence of an entire protein-coding

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91. See, e.g., *Genetics and the Law*, *supra* note 6 (discussing the pros and cons of the types of protection utilized to protect ESTs). Genes have been discovered by several groups apparently without the use of an EST, even though an EST encoding part of that gene had been disclosed in a public database. *Id.* An analysis of our hypothetical development cycle also illustrates this conclusion. Bailey's discovered and developed the Uncle Billy gene without using the CO292 EST. Therefore, gene therapy using the Uncle Billy gene would not infringe a CO292 patent with a limited scope of protection, limited to the CO292 EST.

92. 35 U.S.C. § 154(a)(1). Basic patent protection, giving the owner of the patent the right to exclude others from making or using the inventions, would apply to EST patents, as they apply to any other patented invention. *Id.* Therefore, if another scientist uses a patented EST to discover a full-length gene, that scientist has infringed the EST patent. *Id.*

93. See *supra* note 79 for a discussion of publication of U.S. patents.

94. 35 U.S.C. § 112 (1975).

95. See *Genetics and the Law*, *supra* note 6, at 565-70. Pharmaceutical companies have signed large licensing agreements with genomics companies and Universities to obtain access to EST databases. *Id.* It could be argued that the willingness of the pharmaceutical giant Merck to invest a large sum of money to establish a public EST database is evidence that EST discoveries by genomics companies will be supported even if those discoveries are released to the public domain. *Id.* However, the investment by Merck to develop the public EST database is only a fraction of the investment by other companies to gain access to the private databases. *Id.* at 569-70.

96. *Regents*, 119 F.3d at 1566-69; *Fiers*, 984 F.2d at 1166-71.

DNA segment to meet the written-description requirement for claims that encompass that DNA entire segment.<sup>97</sup> Similarly, the CAFC will likely hold that the disclosure of an EST, a partial DNA sequence of a gene, does not meet the written-description requirement for claims encompassing an entire protein-coding DNA segment.<sup>98</sup> An EST is similar to the rat insulin cDNA disclosed in the patent in suit in *Regents* in that it is a useful probe for isolating a full-length human cDNA, but does not reveal the complete DNA sequence of that cDNA.<sup>99</sup>

*E. Factual Variations on EST Discoveries and the Written-Description Requirement*<sup>100</sup>

It could be argued that the disclosure of an EST sequence, and the deposit of an apparently full-length cDNA that contains the EST, meet the written-description requirement for the entire cDNA.<sup>101</sup> This argument fails, however, even where an inventor discloses dual ESTs apparently representing both ends of a cDNA.<sup>102</sup> A partial DNA sequence disclosure does not precisely define the complete DNA sequence, "such as by structure, formula, chemical name, or physical properties."<sup>103</sup>

This conclusion is the result of several considerations. First, based on a partial sequence determination, an inventor cannot unequivocally demonstrate that he has deposited a complete cDNA.<sup>104</sup> Therefore, the inventor would not prove to the Patent Examiner that he or she is in possession of the entire claimed invention.<sup>105</sup> Second, if the PTO awards claims encompassing an

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97. *Regents*, 119 F.3d at 1566-69; *Fiers*, 984 F.2d at 1166-71.

98. *Regents*, 119 F.3d at 1566-69; *Fiers*, 984 F.2d at 1166-71.

99. *Regents* 119 F.3d at 1567.

100. See Adams et al., *supra* note 25 and sources cited in note 40 (showing that it is difficult to make generalizations for ESTs because of the almost unlimited factual variations surrounding their discoveries).

101. See *Fiers*, 984 F.2d at 1169-70 (agreeing with the PTO Board in holding that a particular segment of DNA was not described because it "did not disclose the nucleotide sequence or 'an intact complete gene'").

102. See *supra* note 40 and accompanying text for a discussion of EST databases that have been generated containing ESTs from both ends of the insert.

103. *Fiers*, 984 F.2d at 1171.

104. See generally Adams et al., *supra* note 25 (indicating that partial cDNAs were favored over complete cDNAs and indicating the average length of an EST was far less than the average size of a complete cDNA). Even where mRNA size determinations appear to match the cDNA insert size, it cannot be determined with certainty that the cDNA is complete until it is sequenced. See, e.g., Papadopoulos et al., *supra* note 30 (exemplifying the use of a comparison of mRNA size to insert size to determine whether an entire insert is present).

105. See *Fiers*, 984 F.2d at 1169-70 (indicating that an inventor must possess the entire gene to possess the entire claimed invention, if the claims

entire cDNA based on the disclosure of only a portion of the cDNA, as provided by an EST, the possibility remains that a multitude of patents claiming an identical cDNA will be awarded, which violates patent laws.<sup>106</sup> Third, if claimed DNA sequences are not disclosed in their entirety, it becomes too cumbersome for inventors to determine the novelty of DNA sequences they discover since they would have to individually analyze a plethora of segments, which is not feasible. Finally, where an inventor apparently discovers the sequence from an entire cDNA based on combining overlapping EST sequences from independent cDNA clones, the written-description requirement is not met because the inventor has not proven that he possesses the complete DNA segment.<sup>107</sup>

*F. Is the Written-Description Requirement Met for an EST DNA Segment?*

Some experts may argue that a specification that discloses an EST does not satisfy the written-description requirement, even for claims limited to only the EST, because of the inaccuracy of the DNA sequence determination of the EST, or because the inventor has not isolated the EST DNA segment away from other DNA segments on the cDNA. However, the reported accuracy for ESTs appears to be sufficient to provide warning to potential infringing parties of related sequences that may warrant further analysis.<sup>108</sup>

As to the isolation of the EST insert, although it is likely a DNA deposit associated with an EST disclosure contains cDNA segments in addition to the EST, with modern methods and a deposit of a DNA sequence containing the EST, one of ordinary skill in the art could easily isolate the EST DNA segment away from the remainder of the cDNA segment.<sup>109</sup> Since it appears the written-description requirement is met for the ESTs themselves as long as a deposit is made, if two ESTs from the same cDNA reveal the complete sequence of a cDNA, claims encompassing the entire cDNA would be supported.

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encompass that gene).

106. 35 U.S.C. § 101 (1975). For many ESTs in the public databases, even where the ESTs were generated from the ends of a cDNA, many different pairs of flanking ESTs can be found for one gene. *Id.* This multiplicity in ESTs generated from the ends derived from the same gene results from alternate splicing of the gene and incomplete cDNA formation during cDNA synthesis. *Id.* This is true even in the situation where a scientist synthesized the cDNAs starting at one known end of the gene by using poly dT primers. *Id.*

107. See *supra* note 104 for a discussion of the difficulties in determining whether a cDNA is complete from the disclosure of an EST from that cDNA.

108. See *supra* note 35 for a discussion of the reduced DNA sequence accuracy for ESTs compared to traditional sequencing methods.

109. LEWIN, *supra* note 16, at 645.

*G. Written-Description Requirement Applied to Other DNA Fragments Derived from the Human Genome*

The arguments relating to the limited scope of patent protection for ESTs can also be applied to other inventions derived from the human genome, such as isolated complete cDNAs and SNPs. Repetitive and rapid methods have been developed for isolating and sequencing various DNA segments, including complete cDNAs and SNPs.<sup>110</sup> Therefore, considerations regarding the optimal protection of these discoveries are similar to those analyzed above for ESTs.<sup>111</sup> However, the risk of such a limited scope, especially when considering patents based on disclosures containing a thorough characterization of an entire cDNA, is that the resultant claims provide little economic value.<sup>112</sup> A company will not spend large sums of money to develop and characterize a blockbuster gene unless there is some assurance that a skilled artisan cannot easily design around a claim to the gene.<sup>113</sup> In *Regents*, the CAFC held that inventors can obtain broad patent protection for DNA segments, and described in general terms the characterization necessary to support such broad claims.<sup>114</sup> Based on this precedent, inventors can obtain broad patent protection of a DNA segment if a proper characterization of that segment is disclosed.<sup>115</sup>

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110. See Collins et al., *supra* note 43, at 1580-81 (discussing the methods that are being developed for generating large quantities of SNPs at very low cost); Debbie Strickland, *Invitrogen Launches Rapid Cloning System*, 1998 BIO WORLD TODAY 2, 2 (discussing a new technology which allows the rapid and semi-automated cloning and expression of DNA segments which contain entire protein-coding regions of genes).

111. See *supra* note 91 and associated text for a discussion of the optimal intellectual property protection for ESTs.

112. See Kenneth G. Kahine, *Going Beyond the Native: Protecting DNA and Protein Patents*, 15 BIOTECH 183, 183-84 (1997) (discussing the ease of designing around narrow patents relating to recombinant DNA molecules).

113. See Rachel Nowak, *Breast Cancer Gene Offers Surprises, Includes Related Article on the Competition to Find the Gene*, 265 SCIENCE 1796 (1994) (discussing the four year race that took place between researchers to isolate the BRCA 1 gene, which is involved with many inherited breast cancers).

114. See *supra* note 78 and accompanying text for a discussion of the guidelines of the CAFC in *Regents* for obtaining a broad scope of protection for a patent covering DNA segments. Based on this precedent, in our hypothetical situation, since Bailey's extensively characterized the Uncle Billy gene, they could obtain broad protection for this gene that would make it virtually impossible for a competitor to design around. Furthermore, Bailey's could apply the doctrine of equivalents to expand its protection even further. CHISUM, *supra* note 44, § 18.01.

115. *Regents*, 119 F.3d at 1569.



#### IV. PROPOSAL FOR A NEW DIMINISHED PATENT TYPE FOR CERTAIN INVENTIONS DERIVED FROM THE HUMAN GENOME

Based on the preceding analysis, the following proposal is offered. Section A suggests minimum requirements for characterization of DNA segments to assure that patents claiming these sequences meet the written-description requirement of 35 U.S.C. § 112. Section B sets forth possible statutory changes to reduce the term and examination process for patents awarded to minimally-characterized segments of DNA derived from the human genome, including ESTs. Section C recommends that the disclosure of an entire DNA sequence of a gene by overlapping ESTs does not make the entire cDNA obvious under 35 U.S.C. § 103.

##### A. *Disclosure Requirements for Patents which Claim DNA Segments Derived from the Human Genome*<sup>116</sup>

The PTO should require that to meet the written-description requirement for a DNA segment, an inventor must determine the DNA sequence of the entire claimed DNA segment, and if a relatively inaccurate DNA sequencing method was used, must deposit a recombinant DNA vector containing the DNA segment in a public depository.<sup>117</sup> As discussed previously, the requirement for

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116. It is difficult to make general proposals related to ESTs because of the many factual possibilities surrounding EST disclosures, some of which were illustrated in previous sections. Compare Adams et al., *supra* note 25, at 1652 with Boguski & Schuler, *supra* note 35, at 369. Adams described a procedure for generating ESTs by randomly priming partial cDNAs. Adams et al., *supra* note 25, at 1652. Boguski & Schuler, described an approach utilizing dual ESTs representing both ends of a potentially full-length cDNA. Boguski & Schuler, *supra* note 35, at 369. However, the proposal attempts to set minimum requirements and to analyze a few of the variables associated with EST disclosures.

117. The requirements are consistent with CAFC precedent regarding inventions of segments of DNA in requiring that the entire DNA sequence of the DNA fragment be described. See *supra* note 61 and accompanying text for a discussion of the written-description requirements and DNA segments. The CAFC holds that the complete DNA sequence is required to assure that the inventor describes the invention sufficiently to permit a skilled artisan to understand the full invention and to assure that the inventor was in possession of the invention at the time of filing the patent application. *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993). In *Fiers*, the CAFC agreed with the PTO Board in holding that since one of the possible inventors did not reveal the DNA sequence of the invention he did not "reasonably convey to the artisan that the inventor had possession at that time of the . . . later claimed subject matter." *Id.* In addition, the complete DNA sequence of a claimed invention might be required even where deposits of the DNA are made available to the general public so that an inventor is not required to experiment with potentially tens or hundreds of thousands of deposited DNA segments to determine whether a DNA segment is novel. Furthermore,

a determination of the DNA sequence for the entire claimed DNA segment is consistent with CAFC precedent regarding patents to DNA segments. This assures that an unreasonable amount of experimentation relating to characterizing deposited DNA segments is not necessary to allow a determination of novelty for other DNA segments, and decreases the number of patents encompassing identical human genome-derived components of future medical products.<sup>118</sup> A deposit of the DNA segment is necessary to meet the written-description requirement, when a relatively inaccurate DNA sequencing method is used to sequence the segment, to provide assurance that the inventor is in possession of the DNA segment, to make the DNA segment readily available to those skilled in the art, and to allow a confirmation of the DNA sequence if a dispute arises.<sup>119</sup> Based on these requirements, the PTO must not grant broad patent protection that encompasses entire cDNAs or genes based on the disclosure of one or more ESTs within that cDNA or gene. This should hold even where an inventor deposits a DNA segment that appears to, but has not been proven to, contain the entire cDNA.<sup>120</sup>

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refusing to grant patents to an entire cDNA based on an EST disclosure eliminates the possibility that several patents to identical complete protein-coding sequences would be granted, where independent disclosures are made of two unique ESTs derived from the same cDNA.

118. See *supra* note 61 and accompanying text for a discussion of CAFC requirements for DNA segments in meeting the written-description requirement. See also *supra* note 86 and accompanying text for a discussion of the tangled web of intellectual property that could result from patents to ESTs.

119. In requiring the deposit of the DNA sequence to meet the written-description requirement, the proposal touches on an issue not yet addressed by the CAFC with respect to the written-description requirement. However, the CAFC held in *Amgen* that for the best mode requirement it is not necessary to deposit cells containing the claimed recombinant DNA molecule with a public cell bank. *Amgen*, 927 F.2d at 1211. The availability of the deposit to confirm the DNA sequence of a patented segment is important for EST inventions because many of these inventions utilize less-accurate rapid DNA sequencing methods. The PTO Board of Patent Appeals and Interferences indicated in dicta that the written description was not met for a DNA segment with sequencing errors where the DNA segment was not deposited. *Ex parte Maizel*, 27 U.S.P.Q.2d 1662, 1667 (Bd. Pat. App. & Int. 1992). See *supra* note 35 for a comparison of the accuracy of DNA sequencing utilized to generate for ESTs and traditional sequencing methods.

120. The PTO should not award patents to DNA segments derived from the human genome which incorporate "comprising" language in the claims. *Pasahow & Kumamoto*, *supra* note 55, at C34. See *supra* note 56 and associated text for a discussion of the meaning of the term "comprising" in patent claims. Instead, these patents should be required to use "consisting of" language in the claims. See also *supra* note 55 and associated text for a discussion of the meaning of the term "consisting of" in DNA patent claims.

*B. Reduced Patent Term and Examination for Human DNA*

Patents of limited scope should be awarded to ESTs and other DNA segments derived from the human genome. However, there are risks involved in awarding limited patents to ESTs based on the inaccuracy of the sequence determination and the burden of excessive patent protection on marketed medical products.<sup>121</sup> Furthermore, in most cases the discovery of ESTs is rapid, requires minimal inventiveness, and has minimal practical utility of most EST discoveries, whereas the process of examining patent applications claiming these ESTs is time-consuming and expensive.<sup>122</sup>

With the foregoing considerations in mind, Congress and the biotech community must consider implementing a special patent category for patents to human DNA segments where a medical or industrial utility is not demonstrated. This special patent category would award a limited term based on a diminished examination process.<sup>123</sup> For example, a five-year term can be appropriate for these patents, although such a determination requires considerable comment from the biotech community before implementation.<sup>124</sup> To minimize the resource requirements for the

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121. See *supra* note 35 and accompanying text for a discussion of the inaccuracy of EST sequence determinations compared to traditional sequence determinations. See also *supra* note 86 and accompanying text for a discussion of the complex web of intellectual property that may result from awarding nonprovisional patents based on EST disclosures.

122. See *supra* note 32 and accompanying text for a discussion of the limitations of EST technology and *supra* note 10 for a discussion of the burdens on the PTO of examining EST patent applications.

123. See Adler, *supra* note 6, at 913.

Perhaps patenting is not the optimal system when unprecedented volumes of data about informational molecules are published. A registration system, like copyright, might be simpler and more affordable. To encourage the development of other important technologies, federal laws were enacted to create new intellectual property systems that would protect novel plant varieties and semiconductor chip masks. This approach might be necessary for DNA sequence inventions.

*Id.* The proposed diminished category is different than the provisional type of patent currently available in the U.S. because an examination is required to obtain a patent under the proposed category, and all of the required parts of the application would be required, including claims. See *supra* note 50 and accompanying text for a discussion of the provisional patent application. However, the proposed new category could be set up like a provisional application in that it could be converted into a nonprovisional patent if, for example, information regarding the utility of the EST related to human disease is disclosed before the shortened term ends. *Id.*

124. This term determination should consider the possible delay in marketing a medical breakthrough as a result of the owner of an EST patent exercising his patent right to exclude others from using patented ESTs. In addition, the term should provide enough time for a company to sufficiently

PTO, the examination process for these patents can be standardized, and reliance can be placed on an inventor regarding the determination of novelty and non-obviousness.<sup>125</sup> The inventor could establish the novelty and non-obviousness of his EST invention by determining that no matches are contained in public DNA databases.<sup>126</sup> Furthermore, it is proposed that the utility requirement could be met by an inventor simply by disclosing that the DNA sequence is derived from the human genome.<sup>127</sup> Therefore, the examination process for EST discoveries could be extremely diminished, thus requiring minimal PTO resources and an accelerated approval process.<sup>128</sup> In addition, the infringing uses excluded by this class of inventions should include only those associated with the physical piece of DNA and not the DNA sequence information contained in a database.<sup>129</sup> This preserves the inclusion of the DNA sequence in functional databases where it can be used along with thousands of other sequences to identify target genes.<sup>130</sup>

### *C. Obviousness of Complete cDNAs and Overlapping ESTs*

The PTO and courts should hold that a complete cDNA is not rendered obvious as the result of overlapping EST sequences.<sup>131</sup> The rationale for this proposal is that if overlapping ESTs do not

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characterize a DNA segment so as to determine its potential uses for which it can file a standard nonprovisional application and possibly obtain the filing date of the "diminished" patent. See, e.g., M.P.E.P. § 2133.01 (discussing effective filing dates of continuation-in-part applications).

125. 35 U.S.C. §§ 102, 103 (1975).

126. See *supra* note 39 and accompanying text for a discussion of the public databases currently available which could be used by an inventor in their search for novelty and obviousness. For the inventor's search for novelty and obviousness to be effective, the EST sequence must be deposited in a public database when EST patents are issued, at the latest. *Id.*

127. Marshall, *supra* note 9, at 643. "Several possible changes could be made [to deal with the huge backlog of EST patents, PTO commissioner] Lehman says. The PTO could ask DNA sequence applicants to do more background research themselves." *Id.* The utility requirement is met, *a priori*, by all DNA discoveries from the human genome since they can be used as probes for a particular chromosome or set of chromosomes or as markers for particular chromosome locations. See Adams et al., *supra* note 25, at 1654 (indicating that more than half of the human ESTs they identified were mapped to certain chromosomes).

128. See *supra* note 10 and accompanying text for a discussion of the current backlog in the PTO.

129. See Thorner, *supra* note 55, at 1024 (describing benefit of patent system to allow those skilled in the art to use information disclosed in patent, but not invention).

130. See *supra* note 43 for a discussion of functional databases.

131. This is a modification of the CAFC's reasoning that if a claimed DNA molecule is not obvious it is not described. *Regents*, 119 F.3d at 1567.

adequately describe an entire cDNA, it follows that such sequences do not make an entire cDNA obvious. There is no single isolated DNA molecule that includes the whole sequence. This is especially important since the plethora of public and (apparently soon to be patented) private EST sequences in combination may reveal the complete DNA sequence of hundreds or thousands of complete protein-coding regions.<sup>132</sup> By preserving the patentability of sequences containing complete protein-coding regions, the PTO and courts provide inventors a sufficient incentive to isolate and characterize entire protein-coding segments of genes.

### CONCLUSION

The risks posed by granting broad patent protection based on EST disclosures are illustrated by considering what could happen if Mr. Potter owns these broad patent rights. Fortunately, the CAFC narrowly construes patent rights based on disclosures of DNA sequences, and as a result, will likely invalidate patent claims based on EST disclosures that contain a broad scope of protection encompassing a gene or even an entire protein-coding segment of a cDNA. The PTO should award narrow claims to ESTs such that the written-description requirement that the CAFC has established is met and the development of innovative medical products continues. Furthermore, to establish optimal patent protection for DNA sequences derived from the human genome, Congress, the PTO, and the biotech community should consider implementing a new limited patent category with a reduced term and decreased examination scrutiny.

After Clarence, a patent attorney in his previous life, informs George Bailey that it is unlikely the CAFC will uphold broad patents based on EST disclosures, George is overjoyed and pleads with Clarence to grant him another chance at life so that he can make certain that the launch of gene therapy based on the Uncle Billy gene is successfully completed. Remember, no inventor is a failure who has a good patent attorney.<sup>133</sup> "Atta Boy, Clarence!"<sup>134</sup>

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132. See *UniGene*, *supra* note 39 (discussing the possibility that overlapping ESTs exist which reveal the entire DNA sequence of a cDNA).

133. See *Wonderful Life*, *supra* note 2 (including a letter from Clarence to George: "Dear George, remember no man is a failure who has friends . . .").

134. *Wonderful Life*, *supra* note 2.