

Abstract

Katrina McClatchey is a 2004 graduate of the University of Oklahoma College of Law and an associate at the Oklahoma City law firm of Dunlap, Coddling & Rogers, P.C. Below, Ms. McClatchey discusses the function and jurisdiction of the European Patent Convention (EPC) treaty and the European Patent Office (EPO) that the treaty established. The EPO issues a single patent that is enforceable in as many countries as the applicant wishes to designate. This makes obtaining patent protection in many European countries not only possible but extremely efficient as well. While the requirements for a European patent are similar to the requirements for a United States patent, Ms. McClatchey highlights some important distinctions of which biotechnologists should be aware.

Edited by Steve Ruby

**THE EUROPEAN PATENT OFFICE AND THE EUROPEAN PATENT: AN OPEN AVENUE FOR BIOTECHNOLOGISTS AND “LIVING INVENTIONS”**

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**I. Introduction**

Biotechnological research and product development relating to living organisms, such as microorganisms as well as plants and animals, have become expanding industries. In order to exploit the commercial potential of new innovations, biotechnologists can seek protection under a patent, much like what has been done in the past for non-living inventions.

Generally, a patent grants an inventor the exclusive right to make commercial use of an invention for a limited time. This adds value to the invention because, under the protection of a patent, an inventor can stop others from making, using or selling the invention without the inventor's authorization. However, patents are legal titles which are territorial in nature. This means that a patent only offers protection within the territorial boundaries of the country that grants the inventor the patent. In other words, there is no such thing as a “worldwide” patent. Therefore, an inventor must file for and obtain a patent in each country where protection is desired.

Various countries around the world, each with a unique culture, have responded differently to the notion of patenting “life.” However, patent systems in Europe have undergone recent developments which are more readily adaptive to technological changes and industrial advancements. These developments have overcome some of the prior hostility toward the patenting of living organisms and offer encouraging prospects for a biotechnology market. Thus, as a general overview, this eBrief will discuss one major avenue in Europe which is open to biotechnologists seeking protection of their work relating to microorganisms, plants and animals: the European patent.

## **II. Background of the European Patent Convention and the European Patent Office**

When protection is sought in a number of countries, an inventor can be faced with multiple legal systems, patent authorities, procedural and substantive requirements, time limitations, costs, language barriers, etc. To help ameliorate such burdens faced by an applicant, and thus facilitate the patent process in Europe, some European countries have joined together under a treaty known as the European Patent Convention (EPC)<sup>1</sup>, under which the European Patent Office (EPO)<sup>2</sup> was created. For EPC member countries, the EPO acts as a central searching and examining authority for patent applications, and grants European patents for patent applications which qualify under certain standard rules. The EPC sets forth the framework for

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<sup>1</sup> The European Patent Convention, also known as the Convention on the Grant of European Patents, was signed in Munich on Oct. 5, 1973 and entered into force in Oct. 7, 1977. Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 268, <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN> [hereinafter EPC]. Presently, contracting member states to the EPC include Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom. Some non-member countries that have been extended protection of the EPO through agreements include Albania, Latvia, Lithuania, and the former Yugoslav Republic of Macedonia. Mewburn Ellis, LLP, *What Is a European Patent?*, at <http://www.mewburn.com/pateutxt.htm> (last visited Oct. 26, 2004).

<sup>2</sup> The European Patent Office (EPO) is the executive arm of the European Patent Organisation, an intergovernmental body set up under the EPC. The EPO received the first European patent applications on June 1, 1978. European Patent Organisation, *Facts and Figures* (2002), at [http://www.european-patent-office.org/epo/facts\\_figures/facts2001/pdf/facts\\_figures\\_01.pdf](http://www.european-patent-office.org/epo/facts_figures/facts2001/pdf/facts_figures_01.pdf).

how the EPO is to operate by determining what constitutes a patentable invention and the process of obtaining and maintaining a European patent.

Through the EPO, an applicant can file and prosecute a single patent application in one language (English, French, or German).<sup>3</sup> If granted by the EPO, a European patent results in a national patent in as many member countries as the applicant wishes to designate.<sup>4</sup> While the applicant may be required to file additional translations for the designated countries, the cost of these translations is not expended by the applicant until after being assured that the EPO will grant a European patent on the application.<sup>5</sup> As such, the EPO application process allows the applicant to avoid the time and expense of filing and prosecuting separate patent applications in various languages before the national patent offices of the member countries.<sup>6</sup>

Once a patent is granted and formalities such as translations and payment of fees have been complied with, the effect of a European patent in any country in which it is in force is the same as that of a national patent issued in that country.<sup>7</sup> Questions of infringement for a granted European patent are left to the national law in each individual member country in which protection is sought.<sup>8</sup> In interpreting the scope of the European patent, the EPC instructs member countries that “[t]he extent of protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description

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<sup>3</sup> EPC, *supra* note 1, art. 14(1).

<sup>4</sup> *Id.* arts. 3, 79(1). The designation of a contracting country is subject to the payment of a “designation fee”. *Id.* art. 79(2). In addition to designation fees, an inventor may also wish to consider other factors such as related expenditures (translation costs for example), where protection is desired (where the invention would be marketed and/or manufactured for example), or where competitor markets or manufacturers are located; and the feasibility of markets, (in countries with high regulatory and approval requirements for example).

<sup>5</sup> EPC, *supra* note 1, art. 65(1).

<sup>6</sup> Taking into account the fees paid in the course of the grant procedure, representation fees for one qualified representative, and the cost of conducting the procedure in only one language, the cost of obtaining a European patent is approximately the same as cost of obtaining three to four national patents. The Guide for Applicants, Part 1, ch. A, § IV, point 22, [http://www.european-patent-office.org/ap\\_gd/index.htm](http://www.european-patent-office.org/ap_gd/index.htm) (last visited Feb. 25, 2004).

<sup>7</sup> EPC, *supra* note 1, arts. 2(2), 64(1).

<sup>8</sup> *Id.* art. 64(3).

and drawings shall be used to interpret the claims.”<sup>9</sup> Other requirements the EPC imposes on its member countries provide that:

- the European patent has a term of 20 years from the filing date<sup>10</sup> (with the possibility of extension in cases of national emergency<sup>11</sup> or to compensate for marketing delay caused by the need for obtaining approval from a governmental entity),<sup>12</sup>
- process patents confer protection on products directly obtained by the process,<sup>13</sup> and
- the collection of compensation for use of the invention after the application is published, but before the patent is granted, must be provided for in circumstances where liability under national law for infringement of a national patent would exist<sup>14</sup> (provided that, if required by the member country, a translation of the claims pending in the application were filed in the national patent office of the country where such collection is pursued).<sup>15</sup>

### III. EPC Requirements for European Patent

For a biotechnologist to obtain the protection of a European patent for a living-invention, certain substantive requirements set forth by the EPC must be met. For an invention to be patentable, it must be “new,” involve an “inventive step,” and be susceptible to “industrial application.”<sup>16</sup> These requirements are similar to (but not entirely the same as) the United States patentability requirements of “novelty,”<sup>17</sup> “non-obviousness”<sup>18</sup> and “usefulness.”<sup>19</sup> Summarily, novelty requires that the invention not form a part of the “state of the art,”<sup>20</sup> i.e. the invention must not be a part of the information or knowledge made available to the public by means of

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<sup>9</sup> *Id.* art. 69(1).

<sup>10</sup> *Id.* art. 63(1).

<sup>11</sup> *Id.* art. 63(2)(a).

<sup>12</sup> *Id.* art. 63(2)(b).

<sup>13</sup> *Id.* art. 64(2).

<sup>14</sup> *Id.* art. 67(2).

<sup>15</sup> *Id.* art. 67(3).

<sup>16</sup> *Id.* art. 52(1).

<sup>17</sup> 35 U.S.C. § 102 (2000).

<sup>18</sup> *Id.* § 103.

<sup>19</sup> *Id.* § 101.

<sup>20</sup> EPC, *supra* note 1, art. 54(1).

written or oral description, use, or any other way, before the filing date of the patent application disclosing the invention.<sup>21</sup> An invention involves an inventive step “if having regard to the state of the art, it is not obvious to a person skilled in the art.”<sup>22</sup> An invention is susceptible of industrial application “if it can be made or used in any kind of industry, including agriculture.”<sup>23</sup>

Furthermore, an invention must also be within the patentable statutory subject matter, i.e. it must be the type of subject matter to which protection will be afforded. This area is where most biotechnology inventors face the most burdensome hurdles when trying to obtain patent protection around the world, as some countries may not recognize living organisms as “patentable subject matter.” With regard to the EPC, there are not details of what qualifies as a patentable “invention,” but there is a non-exhaustive list of things that “shall not be regarded as inventions.”<sup>24</sup> In general, the items on this list are either abstract and/or non-technical (in contrast to being concrete and of technical character).<sup>25</sup> More particularly, the EPC provides that the following shall not be regarded as “inventions:”

- “discoveries, scientific theories and mathematical methods;”<sup>26</sup>
- “aesthetic creations;”<sup>27</sup>
- “schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;”<sup>28</sup> and
- “presentations of information.”<sup>29</sup>

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<sup>21</sup> *Id.* art. 54(2).

<sup>22</sup> *Id.* art. 56.

<sup>23</sup> *Id.* art. 57.

<sup>24</sup> Guidelines for Examination, Part C, ch. IV, § 2.1, at [http://www.european-patent-office.org/legal/gui\\_lines/index.htm](http://www.european-patent-office.org/legal/gui_lines/index.htm) (last visited Feb. 25, 2004).

<sup>25</sup> *Id.*

<sup>26</sup> EPC, *supra* note 1, art. 52(2)(a).

<sup>27</sup> *Id.* art. 52(2)(b). For example, paintings and sculptures with no technical features would not be patentable. Guidelines for Examination, *supra* note 24, § 2.3.4.

<sup>28</sup> EPC, *supra* note 1, art. 52(2)(c). For example, a scheme for learning a language, a method of solving crossword puzzles, a game as an abstract entity defined by its rules, or a scheme for organizing a commercial operation as such would not be patentable. Guidelines for Examination, *supra* note 24, § 2.3.5.

However, these prohibitions are applicable only to the extent that a European patent application or European patent relates to such subject-matter or activities “as such.”<sup>30</sup> Thus, if the application relates to technical subject-matter beyond the abstract or non-technical subject-matter, such that the content of the claimed subject-matter as a whole has a technical character, then there may be a patentable invention.<sup>31</sup>

Most applicable to the biotechnology community is the exclusion from patentability of “discoveries, scientific theories and mathematical methods.”<sup>32</sup> Finding a new property of a known material or article, or finding a previously unrecognized substance occurring in nature, is a mere “discovery” which does not have technical effect and, therefore, is unpatentable as such.<sup>33</sup> However, if that new property is put to practical use, or if the substance found in nature can be shown to produce a technical effect, then it constitutes an invention that may be patentable.<sup>34</sup> For example, if a substance occurring in nature (e.g. a microorganism) is found to have an antibiotic effect, then such use and the substance itself may be patentable as aspects of the invention.<sup>35</sup> Similarly, a gene discovered to exist in nature may be patentable if a technical effect is revealed (e.g. its use in making a certain polypeptide or in gene therapy).<sup>36</sup> Further, biological material<sup>37</sup> that is isolated from its natural environment or produced by means of a technical process can also be patentable, even if it previously occurred in nature.<sup>38</sup>

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<sup>29</sup> EPC, *supra* note 1, art. 52(2)(d). For example, a representation of information, such as spoken words or a book, which lacks technical features and which is defined solely by the content of the information it contains is not patentable. Guidelines for Examination, *supra* note 24, § 2.3.7.

<sup>30</sup> EPC, *supra* note 1, art. 52(3).

<sup>31</sup> Guidelines for Examination, *supra* note 24, § 2.2.

<sup>32</sup> See Guidelines for Examination, *supra* note 24, Part C, ch. IV.

<sup>33</sup> *Id.* § 2.3.1.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> “Biological material” is defined as “any material which contains genetic information and is capable of reproducing itself or being reproduced in a biological system.” Implementing Regulations to the Convention on the

“Scientific theories” are more generalized forms of discoveries and, as such, are evaluated under the same principles.<sup>39</sup> For example, while the physical theory of semiconductivity would not be patentable as such, new semiconductor devices, or processes for manufacturing the semiconductor devices, may be patentable.<sup>40</sup> “Mathematical methods” are considered purely abstract and thus are not patentable as such.<sup>41</sup> For example, a shortcut method of division would not be patentable.<sup>42</sup> However, a calculating machine constructed to operate according to this method may be patentable.<sup>43</sup>

Additionally, “methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body” are not regarded as inventions that are susceptible of industrial application.<sup>44</sup> However, this provision does not apply to products, in particular substances or compositions, for use in any of these methods.<sup>45</sup>

#### IV. Unpatentable Exceptions to the EPC

Furthermore, and of particular importance to a biotechnology inventor of a living organism, the EPC also provides “exceptions to patentability,” wherein European patents will not be granted for inventions that are “contrary to ‘ordre public’ or morality,”<sup>46</sup> or for “plant or animal varieties or essentially biological processes for the production of plants or animals.”<sup>47</sup> Irrespective of the connotation of these prohibitions on patentable subject matter, living matter

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Grant of European Patents, Dec. 13, 2001, Rule 23b(3), at <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG> (last visited Feb. 20, 2004) [hereinafter Implementing Regulations].

<sup>38</sup> *Id.* Rule 23c(a).

<sup>39</sup> Guidelines for Examination, *supra* note 24, § 2.3.2.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* § 2.3.3

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> EPC, *supra* note 1, art. 52(4).

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* art. 53(a).

<sup>47</sup> *Id.* art. 53(b).

does not appear, in a practical sense, to be entirely excluded from patentability under the EPC. As a general matter, the EPO case law appears more adaptive to technological progress by adopting a general attitude that “the purpose of a law (*ratio legis*) is not merely a matter of the actual intention of the legislators at the time when the law was adopted but also of their presumed intention in the light of changes in circumstances which have taken place since then.”<sup>48</sup> Moreover, EPO case law and regulations implementing the EPC tend to interpret the EPC exceptions to patentability narrowly, thus maintaining the European patent as a real possibility for living inventions.

Summarily, under the “ordre public or morality” exception, “[i]nventions, the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to the culture inherent in European society and civilization are to be excluded from patentability as being contrary to morality.”<sup>49</sup> However, exploitation is not contrary to ordre public or morality merely because it is prohibited by law or regulation in some or all of the member states.<sup>50</sup> Further, a survey or opinion poll showing that a particular group of people (or even a majority of the population) in some or all of the member states oppose the granting of a patent for a specified subject-matter, cannot serve as a sufficient criterion for establishing that the subject-matter is contrary to ordre public or morality.<sup>51</sup>

More specifically, the concept of “ordre public” covers the protection of public security, the physical integrity of individuals as part of society, and the environment.<sup>52</sup> Thus, if exploitation of an invention would “seriously prejudice the environment,” it may be contrary to

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<sup>48</sup> HARVARD/Onco-mouse (T19/90), [1990] E.P.O.R. 501, 510.

<sup>49</sup> PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors (T356/93), [1995] E.P.O.R. 357, 366.

<sup>50</sup> EPC, *supra* note 1, art. 53(a).

<sup>51</sup> PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, *supra* note 49, at 369.

<sup>52</sup> *Id.* at 366.



ordre public.<sup>53</sup> However, more than a “possibility” of undesired or destructive effects resulting in damage to the environment (such as for example the transfer of herbicide resistant genes to weeds) may be required to show a sufficient threat to the environment.<sup>54</sup> Furthermore, seeds and plants, *per se*, do not constitute exceptions to patentability merely because they represent living matter or on the ground that plant genetic resources should remain the common heritage of mankind.<sup>55</sup>

Exploitation resulting in the suffering of animals, or other possible risks to the environment posed by the introduction of genetically manipulated animals, may implicate the “ordre public or morality” exception.<sup>56</sup> However, such considerations should be balanced carefully against the invention’s usefulness to mankind when deciding whether or not the exception will bar patenting of the invention.<sup>57</sup> For example, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal are specifically unpatentable, along with animals resulting from such processes.<sup>58</sup>

Other specific biotechnological inventions which remain unpatentable as being contrary to ordre public or morality pertain to the integrity of humans.<sup>59</sup> These include processes for cloning human beings,<sup>60</sup> processes for modifying the germ line genetic identity of human beings,<sup>61</sup> and uses of human embryos for industrial or commercial purposes.<sup>62</sup>

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 372.

<sup>55</sup> *Id.* at 368.

<sup>56</sup> HARVARD/Onco-mouse, *supra* note 48, at 513.

<sup>57</sup> *Id.*

<sup>58</sup> Implementing Regulations, *supra* note 37, Rule 23d(d).

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* Rule 23d(a).

<sup>61</sup> *Id.* Rule 23d(b).

<sup>62</sup> *Id.* Rule 23d(c).

Under the exception to “plant and animal varieties,” “[n]o general exclusion of inventions in the sphere of animate nature can be inferred.”<sup>63</sup> The exception has been literally, and narrowly, interpreted to mean that biotechnological inventions which concern plants or animals can be patentable, provided that the patent application is not technically confined to a single plant or animal variety.<sup>64</sup> With regard to plants,<sup>65</sup> a claim which does not individually claim or identify specific plant varieties is not excluded from patentability, even if it embraces or may embrace one or more plant varieties.<sup>66</sup> Also, a claim to a process for the production of a plant variety is not excluded from patentability merely because the resulting product constitutes a plant variety.<sup>67</sup> With regard to animals,<sup>68</sup> the exception to patentability for animal varieties has been interpreted to apply only to certain categories of animals, but not to animals in general.<sup>69</sup> Therefore, if the subject-matter of the claimed invention is not limited to the categories defined by the terms used in the EPC, i.e. “animal variety” (in English), “race animale” (in French), and “Tierart” (in German), then the exception to patentability does not apply.<sup>70, 71</sup>

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<sup>63</sup> CIBA-GEIGY/Propagating material (T49/83), [1979-85] E.P.O.R. C758, 759.

<sup>64</sup> Implementing Regulations, *supra* note 37, Rule 23c(b).

<sup>65</sup> For a more comprehensive discussion on the application of the “plant varieties” exception, see Katrina McClatchey, *The Effect of the “Onco-Mouse” Decisions on the Exception to Patentability for “Animal Varieties” Under the European Patent Convention*, 2 OKLA. J.L. & TECH. 22 (2004).

<sup>66</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R. 303, 319.

<sup>67</sup> *Id.*

<sup>68</sup> For a more comprehensive discussion on the application of the “animal varieties” exception, see Katrina McClatchey, *The Impact of Novartis on the European Patent Convention’s Exception to Patentability for “Plant Varieties”*, 2 OKLA. J.L. & TECH. 21 (2004).

<sup>69</sup> HARVARD/Onco-mouse, *supra* note 48, at 511.

<sup>70</sup> *Id.*

<sup>71</sup> After being remitted the task of interpreting the concept of “animal varieties” and its counterparts, and applying it to claims for “rodents” and non-human “mammals”, the Examining Division of the EPO found that “rodents or even mammals constitute a taxonomic classification unit much higher than species (‘Tierart’). An ‘animal variety’ or ‘race animal’ is a sub-unit of a species and therefore of even lower ranking than a species. Accordingly, the subject-matter of the claims to animals per se is considered not to be covered by the above three terms of Article 53(b) EPC.” HARVARD/Onco-mouse, [1991] E.P.O.R. 525, 526.

“Essentially biological processes for the production of plants or animals” are also unpatentable under the EPC.<sup>72</sup> However, this provision does not apply to “microbiological processes” or the “products thereof.”<sup>73</sup> Whether or not a process is “essentially biological” depends on the essence of the invention, considering the amount of human intervention and its impact on the result achieved.<sup>74</sup> However, human intervention alone is not sufficient to make the process not “essentially biological.”<sup>75</sup>

A process for the production of plants or animals is essentially biological if it consists entirely of “natural phenomena,” such as crossing or selection.<sup>76</sup> For example, a method of crossing, inter-breeding, or selectively breeding animals (e.g., horses) by merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable.<sup>77</sup> On the other hand, a process of treating a plant or animal to improve its properties or yield, or to promote or suppress its growth (e.g., a method of pruning a tree) would not be considered “essentially biological” because, although a biological process is involved, the essence of the invention is technical.<sup>78</sup> The same could apply to a method of treating a plant characterized by the application of a growth-stimulating substance or radiation, or to the treatment of soil by technical means to suppress or promote the growth of plants.<sup>79</sup>

Biotechnological inventions involving a microbiological or other technical process, or a product obtained by means of such a process (other than a plant or animal variety) are

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<sup>72</sup> EPC, *supra* note 1, art. 53(b).

<sup>73</sup> *Id.*

<sup>74</sup> LUBRIZOL/Hybrid plants (T320/87), [1990] E.P.O.R. 173, 178.

<sup>75</sup> *Id.*

<sup>76</sup> Implementing Regulations, *supra* note 37, Rule 23b(5).

<sup>77</sup> Guidelines for Examination, *supra* note 24, § 3.4.2.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

patentable.<sup>80</sup> A "microbiological process" is "any process involving or performed upon or resulting in microbiological material."<sup>81</sup> The term "microbiological" qualifies activities that include processes which make direct use of microorganisms.<sup>82</sup>

Microbiological activities include fermentation, biotransformation, genetic engineering, chemical engineering, fusion techniques, recombinant techniques, or any other activity in which an integrated use is made of biochemical and microbiological techniques in order to exploit the capacities of microbes and cultured cells.<sup>83</sup> Microorganisms include generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory, such as bacteria, yeast plasmids, viruses, fungi, algae, protozoa and human, animal and plant cells.<sup>84</sup> Thus, "microbiological processes" include processes in which microorganisms (or their parts) are used to make or to modify products, or in which new microorganisms are developed for specific uses.<sup>85</sup> "Products of microbiological processes" include products which were made or modified by microorganisms as well as new microorganisms as such.<sup>86</sup>

## V. Conclusion

In summary, case law, rules, and provisions under the EPC make the EPO, and the European patent, an open avenue for biotechnologists and living inventions. Furthermore, the EPO offers a practical and resource-efficient system in which inventors can obtain protection in multiple member countries by filing and prosecuting a single patent application in one language.

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<sup>80</sup> Implementing Regulations, *supra* note 37, Rule 23c(c).

<sup>81</sup> *Id.* Rule 23b(6).

<sup>82</sup> PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, *supra* note 49, at 378.

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* at 377-78.

<sup>85</sup> *Id.* at 378.

<sup>86</sup> *Id.*

2 OKLA. J. L. & TECH. 25 (2004)

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Such developments encourage technological progress and investment in Europe. As a result, the European patent offers many benefits and commercial opportunities to the biotechnology community, including those involved in research and product development relating to microorganisms, plants, and animals.