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**Protecting Biotechnological Inventions in  
Brazil and Abroad: Draft, Scope and  
Interpretation of Claims**

by

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Originally published in ALBANY LAW JOURNAL OF SCIENCE & TECHNOLOGY  
13 ALB. L.J. Sci. & TECH. 145 (2002)

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# PROTECTING BIOTECHNOLOGICAL INVENTIONS IN BRAZIL AND ABROAD: DRAFT, SCOPE AND INTERPRETATION OF CLAIMS

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## I. INTRODUCTION

In today's increasingly competitive world environment, there is a demand for more sophisticated products that can attend to a large cross-section of society at a reduced cost. Thus, companies and research institutions are compelled to produce a constant flow of a variety of innovative products. In corporate competition, creativity and inventiveness are the key facets of the innovative process in its various forms.<sup>1</sup> These factors are now the main motivating and focalizing instruments for the so-called development policies of science and technology. Studies of the factors that affect technological innovation and that are subject to management and control, reveal that the vast majority of successful innovations come about as a response to demand.<sup>2</sup> Therefore, successful inventions and innovations tend to result from identifying consumer needs at the right time.

This article will present the relevant aspects of patenting in biotechnology and will focus on the drafting of claims and their interpretation passing through the specificities relating to natural products and the sustainable use of genetic resources. Part II of this article will examine the importance of protecting biotechnological inventions.<sup>3</sup> Part III will address Phytomedicines and the use of genetic resources.<sup>4</sup> Part III will also explain the use of traditional knowledge and phytomedicines in Brazil. Part IV will study inventive activity and the sufficiency of disclosure in biotechnology.<sup>5</sup> Part V will explore the scope of claim element of biotechnological patents and will provide examples of claims involving genetic engineering.<sup>6</sup> Part VI will discuss the interpretation of claims,<sup>7</sup> specifically the Japanese Supreme Court's decision in *Sliding Ball Spline*<sup>8</sup> and the United States Supreme

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<sup>1</sup> PAUL A. SAMUELSON, *ECONOMICS* 747 (10th ed. 1976) (recognizing the role of the innovator as an inventor, developer, imitator and successful initiator of technological improvements).

<sup>2</sup> See Erik S. Mauer, Comment, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter*, 95 Nw. U. L. REV. 1057, 1090 (2001) (noting the benefits that society derives from patent activity controlled by market demand).

<sup>3</sup> See *infra* notes 10–50 and accompanying text.

<sup>4</sup> See *infra* notes 51–77 and accompanying text.

<sup>5</sup> See *infra* notes 78–92 and accompanying text.

<sup>6</sup> See *infra* notes 93–155 and accompanying text.

<sup>7</sup> See *infra* notes 156–194 and accompanying text.

<sup>8</sup> *Tsubakimoto Seiko Co. v. THK Co.*, Case No. 1994 (o) 1083 (Feb. 24, 1998), translated in *PATENTS & LICENSING* (1998), available at <http://www.okuyama.com/doe.doc> (last visited Oct. 30, 2002).

Court's holding in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*<sup>9</sup>

## II. PROTECTING BIOTECHNOLOGICAL INVENTIONS

In the area of industrial property, where inventions serve as the basis and origin of innovations, modern companies have the option of protection and exclusive use through the rights conferred by patents.<sup>10</sup> In the field of biotechnology, a decisive factor in assuring financial return from putting a product or process on the market is the choice of protection.<sup>11</sup> For instance, biotechnological inventions, that can easily be obtained by reverse engineering, confirm the need for appropriate protection selection.<sup>12</sup> There are two possible forms of available protection: (i) protection by patent and (ii) protection by trade secret.<sup>13</sup>

If the invention is the product that is to be sold, such as a novel restriction endonuclease, a food processing enzyme, a transfer vector, or a microbial pesticide, the product may be "reverse-engineered" as soon as it is put on sale.<sup>14</sup> In such circumstances, the right to a trade secret is ephemeral; therefore, ultimate reliance must be placed on the patent law.<sup>15</sup> The same conclusion holds true if the trade secret is a novel therapeutic or diagnostic method.<sup>16</sup> What the inventor typically sells is a reagent test kit or

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<sup>9</sup> 122 S. Ct. 1831 (2002).

<sup>10</sup> 35 U.S.C. § 154 (2000) (explaining the contents and terms of a patent).

<sup>11</sup> Shaoyi Alex Liao, *Resolving the Dilemmas Between the Patent Law and Biotechnology: An Analysis of Three Recent Biotechnology Patent Cases*, 11 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 231 (1995) (recognizing patent law as a choice of protection for investors in the field of biotechnology because of the economic incentives it offers).

<sup>12</sup> See Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2477 (1995) (noting that stringent patent protections, such as the TRIPS agreement, are in place to prevent both domestic and international piracy through reverse engineering).

<sup>13</sup> See Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 376 n.53 (2002) (recognizing the difference between trade secret and patent law in that the former is based on secrecy while patent law is based on public disclosure in return for an enforceable patent).

<sup>14</sup> *Id.* at 388.

<sup>15</sup> *Id.* at 387 (according to trade secret law, third party use of a trade secret is only actionable if the secret was obtained by some independent means).

<sup>16</sup> See Jennifer L. Saulino, Note, *Locating Inevitable Disclosure's Place in Trade Secret Analysis*, 100 MICH. L. REV. 1184, 1188 (2002) (defining a trade secret as a secret process or formula that derives commercial value from being kept secret).

apparatus for use in practicing the method.<sup>17</sup> The method must be disclosed to the buyer and cannot be kept as a trade secret.<sup>18</sup>

Conversely, one who is merely selling the final product need not disclose an expression vector, a production organism, or manufacturing method.<sup>19</sup> These types of innovations are suitable for long-term trade secret protection because they involve manufacturing niches created by individual procedures.<sup>20</sup> However, reliance on trade secret protection may not be desirable if the field is one where there is a great deal of research activity.<sup>21</sup> Trade secret law offers no protection against independent developers.<sup>22</sup>

In biotechnological and pharmaceutical fields, where the cost of developing products from research to marketing is very high, the absence of a patent system or a system with an adequate scope of protection would put research at risk.<sup>23</sup> Society would also lose out because it would be deprived of access to the latest drugs for the combat and prevention of various diseases.<sup>24</sup> In the case of biotechnology, there are a high number of legal disputes in proportion to the total number of products.<sup>25</sup> Most of the inventions in this field are refinements of existing inventions; therefore, it is dif-

<sup>17</sup> See Scott D. Anderson, Comment, *A Right Without a Remedy: The Unenforceable Medical Procedure Patent*, 3 MARQ. INTELL. PROP. L. REV. 117, 130 (1999) (noting enforceable patented compositions of matter are "novel uses of drugs, . . . chemical or biological reagents for diagnostic purposes, novel methods for scheduling or timing administration of drugs").

<sup>18</sup> See Kate H. Murashige, *Overview of Potential Intellectual Property Protection for Biotechnology*, 5 RISK 119, 130, 132 (1994) (indicating that trade secret protection is the opposite of patent protection). Patents require full and complete disclosure of protected subject matter. *Id.* at 130.

<sup>19</sup> David G. Majdali, Note, *Trade Secrets Versus the Internet: Can Trade Secret Protection Survive in the Internet Age?*, 22 WHITTIER L. REV. 125, 137-38 (2000) (explaining that consultants and vendors typically sign confidentiality agreements before a company releases trade secret information).

<sup>20</sup> See D. Peter Harvey, *IP Maintenance: Protecting Intellectual Property Assets Through Registration, Proper Use and Contractual Provisions*, in PROTECTING YOUR INTELLECTUAL PROPERTY ASSETS 2001, at 135, 193 (2001) (PLI Pat., Copyrights, Trademarks, & Literary Prop. Course, Handbook Series No. 659, 2001).

<sup>21</sup> See Beckerman-Rodau, *supra* note 13, at 392.

<sup>22</sup> *Id.* at 387-88 (indicating that "rights protected under trade secret law are non-exclusive").

<sup>23</sup> See Carrie F. Walter, Note, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1033 (1998).

<sup>24</sup> See *id.*

<sup>25</sup> John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American system*, 50 EMORY L.J. 101, 172 (2001).

difficult to generate high profit products.<sup>26</sup> Moreover, there is a great deal of dependency and even interdependency between patents.<sup>27</sup> Many countries do not have clearly established guidelines in regard to the scope of protection or the enforcement of patents.<sup>28</sup>

### A. *Patents & the Biotechnological Market*

In spite of all the controversy surrounding biotechnology and the high risk associated to the industry, many investors are becoming "molecule millionaires."<sup>29</sup> To give perspective to the size of the global pharmaceutical industry, in which biotechnology plays an important part, the total market had sales worth over \$300 billion in 1998.<sup>30</sup> Over \$21 billion of this sum was spent on product development, including discovery, completing clinical trials, and obtaining regulatory approval.<sup>31</sup> More than \$10 billion of the total \$300 billion comes in the form of royalties from licensing agreements in force today, accounting for approximately 3.5% of the sales in the sector.<sup>32</sup>

Concerning the market for phytomedicines, many of the world's best-selling pharmaceutical agents are derived from natural products.<sup>33</sup> Plant-based traditional medicine systems have existed for centuries in countries like China and India, and are widely used

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<sup>26</sup> Carlos M. Correa, *Internationalization of the Patent System and New Technologies*, 20 WIS. INT'L L.J. 523, 536 (2002) (explaining how patents can be a defensive tool to either block competitors or to reserve some freedom to operate in the market by relying on the patenting of minor developments).

<sup>27</sup> See *id.*

<sup>28</sup> See generally Robert Blackburn, *Evolving Patent Law in the New Age of Biomedical Science*, 4 TEX. REV. L. & POL. 87 (1999) (discussing the failures of the current U.S. patent law such as scope and enforcement).

<sup>29</sup> See Nuno M. Santos, Note, "Risky Business": EPA Decisions-Making in the Screening of Biotechnological Products, 10 FORDHAM ENVTL. L.J. 229, 230-31 (1999).

<sup>30</sup> *Market Report*, IMS HEALTH (1998) (demonstrating that the U.S. contributed for 11% of the growth, while Europe grew at 4.6% and Latin America 2.2%, while Australia, Africa and Asia declined by 6.8%), available at [http://www.ims-global.com/insight/report/world\\_market/report.htm](http://www.ims-global.com/insight/report/world_market/report.htm) (last visited Oct. 30, 2002).

<sup>31</sup> *Keeping up with Shifting Industry Dynamics*, WORLD PHARMACEUTICAL DEVELOPMENTS (2000), available at <http://www.worldpharmaceuticals.net/eds/drugchemical.html> (last visited Oct. 30, 2002).

<sup>32</sup> R. Ian Lennox, *The Finance Gap*, BIOTECH., Nov. 1999 at 18, 19.

<sup>33</sup> See Robert G. Pinco, *Implications of FDA's Proposal to Include Foreign Marketing Experience in the Over-the-Counter Drug Review Process*, 53 FOOD & DRUG L.J. 105, 110-11 (1998) (explaining that in Europe phytomedicines are a part of nearly every non-prescription drug category; however, in the United States they are only beginning to gain acceptance).

in traditional African health systems.<sup>34</sup> Indigenous communities live in balance with their ecosystem, enabling them to gain knowledge pertaining to organic health and nutrition.<sup>35</sup> This knowledge can become a valuable starting point for the complex research undertaken in the pharmaceutical and biotechnological field, representing gains both in terms of time and money.<sup>36</sup>

For the biotech industry, patent rights are important not only because they guarantee a limited monopoly, but also because they are often a company's only real asset.<sup>37</sup> Patents are therefore vital for obtaining financing, either through venture capital or technology transfer agreements.<sup>38</sup> For investors though, it is not enough to know how many patents a company has; they also need to know the scope of protection and how valuable they are likely to be.<sup>39</sup> However, it is worth remembering, that the debate does not end once a patent application has been filed and subsequently granted. It is very common for rights to be violated, that often involves such large sums of money that the company affected may go bankrupt.<sup>40</sup> During this stage of managing the privilege acquired, potential problems can be minimized through the skill of the patent specialist in drafting the patent application, and particularly in drafting claims.<sup>41</sup>

World practice as to the scope of protection sought through patent applications is defined by the claims filed; thus, claims set the

<sup>34</sup> See Srividhya Ragavan, *Protection of Traditional Knowledge*, 2 MINN. INTELL. PROP. REV. 1, 54, 57 (2001).

<sup>35</sup> Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 233-34 (2001).

<sup>36</sup> *Id.* at 233-35 (noting the collective belief among anthropologists, environmentalist, ethnobiologists, and medical companies that underdeveloped countries are rich in untapped resources).

<sup>37</sup> See Allen C. Nunnally, Note, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 88 B.U. J. SCI. & TECH. L. 306, 388 (2002) (explaining that a biotechnology company's success depends entirely upon obtaining patent protection).

<sup>38</sup> *Id.* at 338-39.

<sup>39</sup> *Id.* at 324 (reporting a sell off in biotechnology stocks and market drop caused by a presidential announcement). Investors perceived the announcement as foreshadowing the narrowing of the scope of patent protection. *Id.*

<sup>40</sup> See Michael J. Guyerson, *Intellectual Property Agreements: Assumption or Rejection Under the Bankruptcy Code*, 21 COLO. LAW. 2377 (1992).

<sup>41</sup> See Peter H. Kang & Kristin A. Snyder, *A Practitioner's Approach to Strategic Enforcement and Analysis of Business Method Patents in the Post-State Street Era*, 40 IDEA 267, 286-87 (2000) (discussing the value in proactive patent searching by patent counsel to prevent infringement or challenges of validity).



limits of the rights conceded by patents.<sup>42</sup> As a result, the scope of protection is not limited to a literal interpretation of the claims; however, a patent does not confer protection to the basic inventive concept or overall inventive concept.<sup>43</sup> This is exactly what is stipulated in Art. 41 of the Brazilian Industrial Property Law of 1996 and what has been the law in Brazil since 1882.<sup>44</sup>

Enforcement options range from simply offering licenses in a patent to full-blown patent infringement litigation.<sup>45</sup> However, before bringing an infringement action several factors must be addressed.<sup>46</sup> These considerations include whether there is a basis for good faith for an infringement lawsuit, whether the patent is valid and enforceable, and what type of damages are available.<sup>47</sup> Therefore, drafting of the patent application and studying of the effects of the scope and interpretation of claims take on a greater importance in guaranteeing the monopoly and competitive advantage of a patent holder over their competitors.<sup>48</sup>

Another issue related to biotechnology is that most genetic resources come from developing countries, but only developed nations have the scientific and technological knowledge and the financial means to exploit these resources.<sup>49</sup> Given that the manufacture of useful products from nature is a business for the firms based in the developed world, it is important for developing countries to regulate access to their genetic resources and their associ-

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<sup>42</sup> Charles N.J. Ruggiero, *Advanced Claim Drafting*, in *ADVANCED CLAIM DRAFTING & AMENDMENT WRITING WORKSHOP 1994*, at 3 (PLI Pat., Copyrights, Trademarks, & Literary Prop. Course, Handbook Series No. 401, 1994); see also 35 U.S.C. § 112 (2000).

<sup>43</sup> See Ruggiero, *supra* note 42, at 3.

<sup>44</sup> See Brazilian Industrial Property Law No. 9279/96 Art. 41 (1996), reprinted in 2C JOHN P. SINNOTT ET. AL., *WORLD PATENT LAW AND PRACTICE*, Brazil 131 (2002) [hereinafter SINNOTT].

<sup>45</sup> See Kang & Snyder, *supra* note 41, at 288.

<sup>46</sup> Edward V. Filardi et al., *Pre-Litigation Considerations Relating to United States Patent Infringement Actions: An Overview*, in *PATENT LITIGATION 9* at 13 (1993) (PLI Pat., Copyrights, Trademarks, & Literary Prop. Course, Handbook Series No. 375, 1993).

<sup>47</sup> See *id.* at 16–18.

<sup>48</sup> See RAYMOND T. NIMMER, *THE LAW OF COMPUTER TECHNOLOGY* § 2:5 (rev. 3d ed. Supp. 2002); see also Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 *YALE L.J.* 777, 778 (1992).

<sup>49</sup> See David G. Scalise & Daniel Nugent, *International Intellectual Property Protection for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 *CASE W. RES. J. INT'L L.* 83, 110–11 (1995).

ated traditional knowledge.<sup>50</sup> Moreover, there must be more discussion about sharing benefits and technology transfer.

### III. PATENTS ON PHYTOMEDICINES & SUSTAINABLE USE OF GENETIC RESOURCES

#### A. *The Use of Traditional Knowledge*

Over the last century, many organizations in developed countries have made use of traditional knowledge and genetic material collected from developing countries.<sup>51</sup> For many years, multinational pharmaceutical companies did not face the inconvenience of having to pay compensation for the samples they obtained from developing countries.<sup>52</sup> But now the relationship between natural resource providers and technological knowledge and financial resource suppliers has changed. In developed countries, research and development institutions, such as the United National Cancer Institute and the University of Mississippi Research Institute of Pharmaceutical Sciences, and pharmaceutical companies like Bristol-Myers Squibb, Glaxo Group, and Merck have set up studies in collaboration with governments and private institutions and are seeking to establish cooperation agreements to screen the potential active substances from plants.<sup>53</sup> This change in behavior is the result of the actions of governments in developing countries and non-governmental organizations, which consider it of fundamental importance that natural resources be preserved and the benefits of the sustainable use of genetic resources be guaranteed for local communities.<sup>54</sup>

Notwithstanding the advances, much more needs to be done for a consensus to be reached. The rights of patent owners must be

<sup>50</sup> See Victoria E. Spier, Note, *Finders' Keepers: The Dispute Between Developed and Developing Countries Over Ownership of Property Rights in Genetic Material*, 7 WIDENER L. SYMP. J. 203, 210 (2001).

<sup>51</sup> See *id.* at 203-04.

<sup>52</sup> *Id.* at 203 ("Historically, naturally occurring genetic material has been categorized as being within the public domain, and thus available for use without compensation."); see also Karen Anne Goldman, Note, *Compensation for Use of Biological Resources Under the Convention on Biological Diversity: Compatibility of Conservation Measures and Competitiveness of the Biotechnology Industry*, 25 LAW & POL'Y INT'L BUS. 695, 705-06 (1994) (noting that this appropriation by developed countries devastated industries of developing countries).

<sup>53</sup> Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 VAND. J. TRANSNAT'L L. 703, 719, 725, 730-31 (1995). The fact that a bilateral plant collection agreement is even in existence is a very recent, albeit, positive step forward. *Id.* at 725.

<sup>54</sup> *Id.* at 714.

balanced against the rights of natural resource owners.<sup>55</sup> Both developed and developing countries, and their populations, can win if they share their rights and responsibilities.<sup>56</sup> This is evidenced by the 121 plant-derived medicines that have been discovered as a result of chemical studies directed at isolating the active ingredients in plants used in traditional medicine.<sup>57</sup> The antihypertensive agent "Reserpine,"<sup>58</sup> the antimalarial agent "Quinine,"<sup>59</sup> and the anti-cancer "Taxol"<sup>60</sup> are examples of plant-derived products which give profits to their manufacturers.<sup>61</sup>

### B. Patents for Phytomedicines in Brazil

It is estimated that Brazil possesses fifteen to thirty percent of the world's plants, vegetables, and animal species, allied to which there is also a bountiful array of cultural diversity.<sup>62</sup> In fact, Brazil's Indigenous groups account for more than 200 distinct cultures.<sup>63</sup> Brazilian legislation, specifically Industrial Property Law No. 9,279/96,<sup>64</sup> considers extracts of plants and active substances present in plants, even such substances isolated there from as dis-

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<sup>55</sup> See *id.* at 715 (explaining Article 19 of the U.N. Convention for Biological Diversity). "Article 19 explicitly states the developing world's expectation that, in exchange for access to its biodiversity, it will receive a fair and equitable portion of the benefits that the North derives from the use of the South's genetic resources." *Id.*

<sup>56</sup> See *id.* at 714.

<sup>57</sup> See Liz Hanellin, Note, *Protecting Plant-Derived Drugs: Patents and Beyond*, 10 CARDOZO ARTS & ENT. L.J. 169, 170 (1991); see Scott C. Lucas, *Halting the Downward Spiral of Monoculturization and Genetic Vulnerability: Toward a Sustainable and Biodiverse Food Supply*, 17 J. ENVTL. L. & LITIG. 161, 173 (2002) ("Currently, one-fourth of all pharmaceuticals in this country [United States] are derived from natural sources.").

<sup>58</sup> *Id.* at 178.

<sup>59</sup> Chetan Gulati, *The "Tragedy of the Commons" in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Office*, 4 YALE HUM. RTS. & DEV. L.J. 63, 71 n.31 (2001).

<sup>60</sup> See Michael J. Huft, Comment, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678, 1680 n.7 (1995).

<sup>61</sup> See Lucas, *supra* note 57, at 173 (stating that sales of plant-derived drugs in the United States exceeds tens of billions of dollars every year). Furthermore, drug companies earn \$30 billion annually from products that contain biological material derived from developing countries. *Id.*

<sup>62</sup> Janelle E. Kellman, *The Brazilian Legal Tradition and Environmental Protection: Friend or Foe*, 25 HASTINGS INT'L & COMP. L. REV. 145, 147 (2002).

<sup>63</sup> See Francisco Weffort, *Brazil: Challenges of a Multiethnic and Multicultural Society*, available at <http://www.minc.gov.br/textos/fw17.htm> (last visited Oct. 8, 2002).

<sup>64</sup> See SINNOTT, *supra* note 44, at 131.

coveries.<sup>65</sup> This is the basis for excluding such products from patentability.<sup>66</sup> However, processes to obtain plant extracts or to isolate active substances from plants, pharmaceutical compositions and processes to prepare pharmaceutical compositions, and even other uses of products obtained from plants are patentable.<sup>67</sup>

In fact, the patentability of medicines has been permitted by Brazilian legislation since 1996,<sup>68</sup> when the Industrial Property Law No. 9,279/96,<sup>69</sup> incorporating the provisions of TRIPS, was enacted.<sup>70</sup> The previous law (Law No. 5,772/71)<sup>71</sup> excluded the right to patent inventions from the food and pharmaceutical fields and chemical products.<sup>72</sup> However, medicine and food products patented abroad before May 14, 1996, could receive protection if the product was not put on the market.<sup>73</sup> The patent applications filed according to Article 230 and Article 231 are known as pipeline patent applications or pipeline granted patents.<sup>74</sup> In the pharmaceutical field, about 550 pipeline patent applications have been filed, but only two relate to plant products, phytomedicines and plant extracts.<sup>75</sup> Another chance to file patent applications for unpatentable subject matter before May 14, 1997, was provided by Article 70.8(a) of the TRIPS Agreement. Patent applications related to medicine have been eligible to be filed in Brazil since January 1, 1995, when TRIPS came into force; however, such patent rights have only been enforceable only since May 14,

<sup>65</sup> See John Giust, *Comparative Analysis of the United States Patent Law and the New Industrial Property Code of Brazil*, 21 HASTINGS INT'L & COMP. L. REV. 597, 602-03 (1998).

<sup>66</sup> See *id.*

<sup>67</sup> Hanellin, *supra* note 57, at 177-78.

<sup>68</sup> See Marilete Tang, *Brazil: New Industrial Property Legislation*, available at <http://www.natlaw.com/pubs/spbrp1.htm> (last visited Oct. 30, 2002).

<sup>69</sup> SINNOTT, *supra* note 44, at 131; see also Christopher S. Mayer, Note, *The Brazilian Pharmaceutical Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?* 12 TEMP INT'L & COMP. L.J. 377, 388 (1998).

<sup>70</sup> Mayer, *supra* note 69, at 387.

<sup>71</sup> *Id.* at 387 n.98.

<sup>72</sup> *Id.*

<sup>73</sup> See Tang, *supra* note 68.

<sup>74</sup> See Mayer, *supra* note 69, at 387. "The pipeline protection allows foreign pharmaceutical companies to obtain patent protection in Brazil for the remainder of the term of their home country." *Id.*

<sup>75</sup> See generally David Merrylees, *Pharmaceutical Patents in Brazil* (July 2001), available at <http://www.ficpi.org/newsletters/48/pharmaceuticals.html> (last visited Oct. 30, 2002). See INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL, at <http://www.inpi.gov.br/idiomas/ingles/index.htm> (last visited Oct. 30, 2002) [hereinafter INPI].

1997, when Law No. 9,279/96 became effective.<sup>76</sup> Due to this possibility, thirty-three patent applications were filed between January 1, 1995, and May 14, 1997.<sup>77</sup>

#### IV. INVENTIVE ACTIVITY AND SUFFICIENCY OF DISCLOSURE IN BIOTECHNOLOGY

Biotechnology is an extremely complex field where there is no longer an individual specialist, but rather a team of specialists that understand the difficulties that are encountered during, for example, the cloning of a gene.<sup>78</sup> Therefore, when the research in question concerns the development of a recombinant vaccine, the professionals involved in the case must come from the areas of immunology, technicians with knowledge of molecular biology, and specialists in the development of bioprocesses.<sup>79</sup> Moreover, questioning by the examiners about the inventive step involved in any invention is becoming increasingly common, and the type of question that is being asked in the field of genetic engineering tends to be as follows: to what extent would it be obvious for one skilled in the art to execute the method that is being proposed with “*a reasonable expectation of success?*”<sup>80</sup> Therefore, the fact that other people or groups are working simultaneously on the same project may suggest that it deals with an area of interest to be exploited or “obviously to be attempted.”<sup>81</sup> Of course, this does not necessarily imply that those involved or intending to become

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<sup>76</sup> See Mayer, *supra* note 69, at 380–81, 387.

<sup>77</sup> See INPI, *supra* note 75. Cf. WIPO Industrial Property Statistics, *25 Years of Industrial Property Statistics (1975–2000)*, (noting that seventy patents were filed during this period), available at <http://www.wipo.int/ipstats/en> (last visited Oct. 30, 2002).

<sup>78</sup> See Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 49 (2001) (explaining that the transnational growth of biotechnology needs to be addressed by society as a whole); see also *Case Law of the Boards of Appeal*, EUROPEAN PATENT OFFICE (discussing the complexity of cloning a gene, and how a team of appropriate specialists are needed to interpret the technicalities of biotechnology), available at [http://www.european-patent-office.org/legal/case\\_law/e/I\\_D\\_5-1-3.htm](http://www.european-patent-office.org/legal/case_law/e/I_D_5-1-3.htm) (last visited Oct. 30, 2002).

<sup>79</sup> See Rachele K. Seide & Janet M. MacLeod, *Drafting Claims for Biotechnology Inventions*, in *ADVANCED CLAIM DRAFTING & AMENDMENT WRITING* 1999, at 381, 385 (PLI Pat., Copyrights, Trademarks, & Literary Prop. Course, Handbook Series No. 585, 1999).

<sup>80</sup> Richard J. Warburg, *From Chemicals to Biochemicals: A Reasonable Expectation*, 24 SUFFOLK U. L. REV. 155, 165, 172–73 (1990); see also 35 U.S.C. § 103 (2000) (showing the statutory obviousness factor in examination of patent applications).

<sup>81</sup> See Warburg, *supra* note 80, at 166–67.

involved will have a reasonable expectation of success.<sup>82</sup> A reasonable expectation of success should not be confused with the desire to be successful.<sup>83</sup>

The fulfilment of the requirement for sufficiency of disclosure has been the subject of heated discussion surrounding patent applications in the field of biotechnology. For patent applications involving new biological materials that cannot be described in such a manner to allow any expert to repeat the inventive process, it becomes necessary for such material to be deposited at an International Depository Authority<sup>84</sup> in compliance with the Budapest Treaty for the Protection of Biotechnological Inventions.<sup>85</sup> Furthermore, some countries, including the United States and Brazil, require that the "best mode" of carrying out the invention known at the time of filing the patent application be mentioned by the inventor.<sup>86</sup> Concerning European legislation, Rule 28(1) of the European Patent Convention<sup>87</sup> cannot be interpreted as the obligation to deposit biological material with the aim of making it easier to reproduce the invention.<sup>88</sup> This is true even though it can be reproduced from a written description, even if this route is more laborious and longer than simply growing the deposited material.<sup>89</sup> This implies introducing the "best mode" requirement into European legislation.<sup>90</sup> It is essential that the specification also contains adequate information about the characteristics defined in the claim.<sup>91</sup> This is important because the laws of individual nations may not allow the description to be supplemented during

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at 169 (acknowledging the motivation factor in considering obviousness).

<sup>84</sup> See Designation of International Depository Authorities Under the Budapest Treaty, 45 Fed. Reg. 61009 (Sept. 15, 1980) (discussing the purpose of the depository requirement).

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

<sup>86</sup> See 35 U.S.C. § 112 (2000); see also Giust, *supra* note 65, at 627.

<sup>87</sup> See Brandi L. Wickline, Note, *The Impact of the Deposit Requirement for Patenting Biotechnology: Present Concerns, Proposed Solutions*, 24 VAND. J. TRANSNAT'L L. 793, 799-800 n.47 (1991).

<sup>88</sup> *Id.* at 821.

<sup>89</sup> *Id.* (stating that the European Patent Convention was an effort to alleviate the hardships of biotech inventors, but it fails to hit the underlying problems of publishing early that Rule 28 was to solve).

<sup>90</sup> See Anthony D. Sabatelli, *Impediments to Global Patent Law Harmonization*, 22 N. KY. L. REV. 579, 593-94, 608 (1995). The World Intellectual Property Organization (WIPO) was implemented to "promote the protection of intellectual property on a worldwide scale." *Id.*

<sup>91</sup> 35 U.S.C. § 112 (2000).

the examination procedure with material that is beyond the scope of the invention that was filed.<sup>92</sup>

## V. SCOPE OF THE CLAIM

Claims are the specificities of the invention for which protection is being requested.<sup>93</sup> More specifically, they are the particular aspects the inventors consider to be novel compared to the present state of the art.<sup>94</sup> In this manner they ascertain and establish the rights of the patent owner over the matter intended for protection.<sup>95</sup> Therefore, the claims themselves are the invention.

### A. *Form of Claims and Terminology Used*

Claim drafting requires clear and compact recitation of the invention in a highly stylized format.<sup>96</sup> The first rule is that claims must be drafted in a single sentence.<sup>97</sup> Most countries require the structure of claims, especially those that are independent, to follow the so-called "Jepson" type claim.<sup>98</sup> These claims typically consist of three parts. Part I of the claim is a preamble, or introductory phrase that summarizes the type of invention, its relation to the prior state of the art, and its intended use or properties.<sup>99</sup> Part II of the claim is a transition connecting the preamble to the body of the claim that indicates whether the invention may include more than the limitations stated in the claim when a judgement must be made as to whether there has been a literal infringement.<sup>100</sup> Part III of the claim is the body, consisting of the elements and limitations which define the fea-

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<sup>92</sup> *Id.*; see also Ted Apple, *Enablement Estoppel: Should Prosecution History Estoppel Arise When Claims are Amended to Overcome Enablement Rejections?*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 107, 124 (1997).

<sup>93</sup> 35 U.S.C. § 102.

<sup>94</sup> *Id.* (providing the requirements for passing the novelty test for claims); see also Joe D. Calhoun, *The Impact of Patent Law on Everyday Practice*, 35 ARK. LAW. 30, 31-32 (2000). "However, novelty does not require that each individual part be previously unknown; in many instances, a new combination of known elements has sufficient novelty to be patentable, as does an improvement to a previous invention." *Id.*

<sup>95</sup> See Robert C. Faber, *Patent Claim Writing*, in FUNDAMENTALS OF PATENT PROSECUTION 2002: A BOOT CAMP FOR CLAIM DRAFTING & AMENDMENT WRITING, 107, 111-12 (2002).

<sup>96</sup> See *id.* at 109, 120.

<sup>97</sup> *Id.* at 120.

<sup>98</sup> See ROBERT C. FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING § 57 (4th ed. 2001).

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

tures of the invention and set the boundaries of the patent monopoly granted to the patentee.<sup>101</sup> This structure is not only recommended but prescribed in the regulations of most national laws, including Brazilian legislation.<sup>102</sup> Although permitted by the United States Patent and Trademark Office (PTO), this structure is rarely used.<sup>103</sup>

The choice of expressions linking the characteristic elements of the invention and the elements known in the state of the art, or between a term of general definition and its alternatives, is an important factor in establishing protection.<sup>104</sup> These linking words tell those examining a patent whether the claim is "open" or "closed" to additional elements.<sup>105</sup> They determine if a claim is limited to structures with *only* these elements ("closed" terminology) or if it is open to structures containing *at least* these elements ("open" or hybrid terminology).<sup>106</sup> Terms such as "comprising," "including," or "having" are "open" forms of definition, and therefore permit the addition of elements, provided they have been foreseen in the description of the invention.<sup>107</sup> The "closed" form of definition can be illustrated by the term "consisting of."<sup>108</sup> The transition phrase "characterised by" is obligatory in Brazil, frequently employed in Germany and Japan, but rarely used in the United States.<sup>109</sup> It is not yet clear whether a claim containing "characterised by" as a linking expression constitutes an "open" or "closed" claim, even though it is generally accepted as constituting an "open" claim.<sup>110</sup>

<sup>101</sup> *Id.*

<sup>102</sup> See Jason M. Okun, Note, *To Thine Own Claim Be True: The Federal Circuit Disaster in Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 21 CARDOZO L. REV. 1335, 1353 (2000).

<sup>103</sup> See FABER, *supra* note 98, § 57.

<sup>104</sup> See Faber, *supra* note 95, at 112, 116–17. The "claim's scope is governed by two requirements." *Id.* at 112. "First, is the requirement of proper claim language, proper in form, so that the claim particularly points out and distinctly claims the invention, and the second, of course, is the state of the prior art, which limits the claim scope." *Id.* The patent practitioner needs to articulate these requirements in a broad manner, encompassing similar inventions, thereby protecting the patent. *Id.* at 116–17.

<sup>105</sup> *Id.* at 121.

<sup>106</sup> *Id.*

<sup>107</sup> See Faber, *supra* note 95, at 121.

<sup>108</sup> *Id.*

<sup>109</sup> TOSHIKO TAKENAKA, INTERPRETING PATENT CLAIMS: THE UNITED STATES, GERMANY AND JAPAN 91 (1995).

<sup>110</sup> *Id.* at 91–92.



### B. *Product and Process Claims*

Having selected the appropriate form of protection, one of the first questions to be raised concerns what is to be patented.<sup>111</sup> A great number of patents relate to methodologies, such as how to produce drugs or clone genes. The decision on what is to be patented should be based on the commercial expectations of the object to be protected.<sup>112</sup> Although obtaining a patent is not difficult, it is important for the patent holder to evaluate the scope of the protection and to determine what the protection is worth. Further, the importance of the balance between the scope of a patent and its validity should be evaluated.<sup>113</sup> Thus, when a party wishes to obtain a patent, it is necessary to define the limits between the invention that must contain an element of novelty, inventive step, as well as, industrial application, and the state of the art.

It is important to note the distinction between claims for products and claims for processes, since the effect of the protection offered by the patent differs according to which category the claim belongs to.<sup>114</sup> A claim for a product covers all the actions involved in producing, using, marketing, selling, buying or importing a product that possesses the structural characteristics described in the claim.<sup>115</sup> However, in Biotechnology, the ability to produce natural products by recombinant and other artificial laboratory techniques creates problems in construing the scope of product claims.<sup>116</sup> Questions that arise are whether a biotechnology product prepared by recombinant or other isolation methods is distinct from the natural product itself, and whether structural variances in an infringing product—compared with the patented product—that functions in a manner similar to the patented product avoid infringement.<sup>117</sup>

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<sup>111</sup> See James W. Dabney, *Fundamentals of Patent Litigation*, in ALI-ABA COURSE OF STUDY, FUNDAMENTALS OF PATENT LAW AND PRACTICE 291 (1994).

<sup>112</sup> Ko, *supra* note 48, at 779–80 (discussing the economic power a patent with a broad scope may have).

<sup>113</sup> *Id.*

<sup>114</sup> Mark D. Passler, Note, *Product-By-Process Patent Claims: Majority of the Court of Appeals for The Federal Circuit Forgets Purpose of the Patent Act*, 49 U. MIAMI L. REV. 233, 233–34 (1994).

<sup>115</sup> *Id.*

<sup>116</sup> See Ko, *supra* note 48, at 783–84.

<sup>117</sup> *Id.*

Article 42, paragraph II of Brazilian Industrial Property Law No. 9279/96<sup>118</sup> provides that the owner of a patent for a process has the right to prohibit third parties from using the patented process and from using, marketing, selling or importing with such purpose the product obtained directly from the patented process.<sup>119</sup> Likewise, national laws and international treaties concerning patents presently recognize the right of the owner of a patent related for a process to the product obtained directly from such process, at the least.<sup>120</sup> Thus, the inclusion of the word “directly” in the above extract could generate some discussion, even though its adoption by Brazilian legislation derives from the TRIPS Agreement.<sup>121</sup> The following analysis will only be made on the need to interpret the range of the word “directly.” In other words, should this expression be interpreted as having a restrictive meaning, or can a product that is being submitted to the patented process and subsequently to additional steps be considered as having been obtained *directly* from the patented process?

The 1990 version of the Patent Harmonization Treaty of the World Intellectual Property Organization (WIPO) included provisions similar to the aforementioned, concerning the inclusion of the word “directly.” However, this provision was removed in later drafts. Nevertheless, in the footnotes of the articles, this draft clarified that the word “directly” was intended to indicate that the right to ownership of a process patent is granted solely to those products that are a direct consequence or result of the use of the process. In other words, if additional steps to the use of the process are required in order to obtain the product, this product cannot be considered a direct result of the use of the process.

The European Patent Convention (EPC)<sup>122</sup> also includes the right to prevent the practice of unauthorized acts related to products obtained directly by a patented process as one of the rights of

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<sup>118</sup> See SINNOT, *supra* note 44, at 131.

<sup>119</sup> *Id.*

<sup>120</sup> See Andrew Y. Piatnicia, Note, *An Evolution of the World Intellectual Property Organization's Draft Harmonization Treaty with Respect to Direct Infringement*, 26 N.Y.U. J. INT'L L. & POL. 375, 395-96 (1994).

<sup>121</sup> Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U. J. INT'L & POL'Y 769, 805 (1997) (discussing how Brazil has ratified the TRIPS Agreement).

<sup>122</sup> European Patent Convention, available at <http://www.european-patent-office.org/legal/epc/> (last visited Oct. 30, 2002).

a patent holder.<sup>123</sup> In a decision passed in a lower court in the England on the use of the word “directly” in British legislation, Judge Aldous sustained that the “directly obtained” product must be the first product of a process, not an intermediate product.<sup>124</sup> Therefore, only the direct result of the process is covered by the protection granted by the patent. Indeed, Judge Aldous supplied the following example to clarify his interpretation:

In a patent for a process relating to the impregnation of textiles, the articles coated by the application of the said process are “directly obtained.” If a patent is equally granted for a process relating to the preparation of an impregnating agent, then the impregnating agent prepared by the application of that process is “directly obtained,” but not the article treated with that agent.<sup>125</sup>

United States legislation does not include “directly” in analogous provisions to those contained in paragraph II, article 42 of the Brazilian Law. However, it does supply exceptions whereby acts relating to a product initially produced by the patented process are not considered an infraction when: “(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.”<sup>126</sup> On determining the range of the word “directly” in a specific case, it must be checked whether a restrictive interpretation would harm or even make it impracticable for the rights assured by the patent of the process in question to be exercised.<sup>127</sup> However, the inclusion of the word “directly” leaves no doubt of the legislator’s intention to impose some restriction on patents for processes regarding the range of products that can be obtained from them, since the main objective is for the wider protection to be conferred on the process itself.<sup>128</sup>

Product-by-process claims define a product in terms of the process by which it is made.<sup>129</sup> These claims are usually included in patent applications as a safeguard in the event the product claims

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<sup>123</sup> See Gretchen Ann Bender, *Clash of the Titans: The Territoriality of Patent Law vs. The European Union*, 40 IDEA 49, 58 (2000) (detailing the European Patent Convention and the respective rights of patent holders).

<sup>124</sup> Fiona Russell & Heidi Hurdle, *What is the Direct Product of a Patented Process*, 17 EUR. INTELL. PROP. REV. 249, 249 (1995).

<sup>125</sup> *Id.* at 251.

<sup>126</sup> 35 U.S.C. § 271 (2000).

<sup>127</sup> See Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 20–21 (2001).

<sup>128</sup> *Id.* at 21.

<sup>129</sup> Passler, *supra* note 114, at 233–34.

are rejected.<sup>130</sup> The PTO routinely grants patents with product-by-process claims, although the sufficiency of patent protection afforded to these claims by the courts is in conflict.<sup>131</sup> The PTO's approach to product-by-process claims parallels its approach to product claims in that if the product is patentable the PTO deems the product-by-process patentable.<sup>132</sup> The patentability of the process does not impact the patentability of the product-by-process.<sup>133</sup>

In order to remove the conflict concerning product-by-process claims, courts must afford novel products that are categorized as product-by-process claims, broad protection under the doctrine of equivalents.<sup>134</sup> The process terms ought to be considered limitations of the claim only when the product being claimed is not novel but is known in the prior art or is obvious.<sup>135</sup> For example, if the product claimed is novel and the result of breakthrough research, it deserves a broad scope of protection against infringement if biotechnology is to be fostered.<sup>136</sup> This broad scope, provided under the doctrine of equivalents, will encourage companies to invest in potential breakthrough research and development and thus help achieve the goals of the patent system.<sup>137</sup> Section VI of this article will provide an in-depth discussion of the doctrine of equivalents.<sup>138</sup>

<sup>130</sup> *Id.* at 234 (describing the product-by-process claims as a protective measure for applicants).

<sup>131</sup> Michael J. Schutte, *Patent Law: Controversy in the Federal Circuit Over Product-By-Process Claims—Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir.), *reh'g en banc denied*, 974 F.2d 1279 (1992), 19 U. DAYTON L. REV. 283, 283 (1993) (discussing how the courts have been in conflict attempting to resolve the issue).

<sup>132</sup> Laurence A. Hymo & Richard A. Anderson, *Product-By-Process Claims: Time for Reexamination*, 3 FED. CIR. B.J. 131, 132–33 (1993) (noting the variety of product claims that have been granted over the years).

<sup>133</sup> *Id.*

<sup>134</sup> See generally Rena Patel, *Doctrine of Equivalents as Applied to Biotechnology Patent Claims*, 18 BIOTECH. L. REP. 221 (1999).

<sup>135</sup> See Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMP. & TECH. L.J. 1, 37 (1991).

<sup>136</sup> See Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 4 FED. CIR. B.J. 243, 250 (1994).

<sup>137</sup> See Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 6 J.L. & POL'Y 741, 791 (1998).

<sup>138</sup> See *infra* notes 156-194 and accompanying text.

### C. Patentability of DNA Sequences

The protection of biotechnological creations are related to highly complex issues, including those regarding the patentability of DNA sequences.<sup>139</sup> When a DNA sequence, coding for a product whose existence was known in the prior state of the art, is cloned for the first time by use of conventional techniques, an unexpected effect of said DNA must be shown by the patent applicant in order to prove that said invention has an inventive step. It is known that for every possible protein there exists at least one corresponding gene in nature. In this sense, the cloning of a DNA sequence (synthetic or native) can be considered as an invention, even when carried out using conventional techniques, if there is some effect that is unexpected when compared with the state of the art.<sup>140</sup>

The extent of protection granted depends upon the knowledge a person skilled in the art would have about the protein in question.<sup>141</sup> In general, it could be said that the more that is known about a protein, the narrower the claims for which an inventive step can be recognized will have to be.<sup>142</sup> If, for example, the amino acid sequence of the protein is known in the prior art, it is clear that the person skilled in the art could easily use a simple computer program to derive all the possible corresponding DNA or RNA sequences coding for it. In this case, the claims should be limited, to the: (i) specific DNA sequence which is selected in a non-obvious way from the possible sequences, and which results in the expression of the derived product in a host cell or (ii) specific host/recombinant vector system which allows such expression. If, on the other hand, the amino acid sequence of the protein was totally unknown in the prior art, then claims of a broader nature may be drafted, by reference to DNA sequence coding for a protein with the following amino acid sequence. In view of the degeneracy of the genetic code, in this last case, additional alternatives for the

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<sup>139</sup> See Sara Dastgheib-Vinarov, Comment, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 143 (2000) (explaining that biotechnology is very "highly patent-sensitive," because of the high risks and the importance of financial rewards).

<sup>140</sup> See, e.g., Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 726-27 (1990).

<sup>141</sup> See *id.* at 730.

<sup>142</sup> See Stephen G. Whiteside, Note, *Patents Claiming Genetically Engineered Inventions: A Few Thoughts on Obtaining Broad Property Rights*, 30 NEW ENG. L. REV. 1019, 1069 (1996).

DNA sequence coding for the said amino acid sequence will be protected.

#### D. *Examples of Claims Involving Genetic Engineering*

##### 1. Genes

In principle, a gene shall be defined by specifying its base sequence.<sup>143</sup> A structural gene shall be characterized by specifying the amino acid sequence of the protein encoded by the gene.<sup>144</sup> A classic example of this type of claim is a gene coding for a protein with an amino acid sequence represented by SEQ ID No: 1.<sup>145</sup> In this case, SEQ ID No: 1 is a sequence of amino acids defined in the specification of the patent application.<sup>146</sup> A broader scope may be established claiming protection not just for SEQ ID No: 1, but also for functional equivalents. In these cases, the genes can be defined by the combined use of functional expressions, such as “deletion, substitution or addition” or “hybridizable,” and a function common to them, if necessary, with their origin and career.<sup>147</sup> Examples are as follows:

- a.) Gene coding for (i) a protein with an amino acid sequence according to SEQ ID No: 1 or (ii) a protein with an amino acid sequence of the protein defined in (i) with deletion, substitution or addition of one or more amino acids and possessing enzymatic activity X.<sup>148</sup>
- b.) A gene comprising (i) a DNA with a base sequence defined in SEQ ID No: 2 or (ii) a DNA of human origin that is hybridizable, under stringent conditions, with a DNA with the base sequence of the DNA defined in (i) and coding for a protein possessing an enzymatic activity Y.<sup>149</sup>

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<sup>143</sup> Diana Sheiness, *Protecting Gene Sequences*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 121, 122 (1996).

<sup>144</sup> *Id.*

<sup>145</sup> 37 C.F.R. § 1.821(d) (2001).

<sup>146</sup> *Id.* § 1.821(b)(c)(d).

<sup>147</sup> See, e.g., Shelia R. Arriola, *Biotechnology Patents After Festo: Rethinking the Heightened Enablement and Written Description Requirements*, 11 FED. CIR. B.J. 919, 927–28 (2002) (using amino acid forms as an example when inserting, adding, deleting, or substituting the original sequence to create a new protein).

<sup>148</sup> See, e.g., JEFFREY G. SHELDON, HOW TO WRITE A PATENT APPLICATION § 14.5.7.1(1)–(6) (2001).

<sup>149</sup> See *id.* at (3)–(7).

A gene can be defined by specifying its function, physico-chemical properties, origin, preparation processes.<sup>150</sup> Claims with either of the two structures cited above are favorable for the applicant, because broader protection can be granted.<sup>151</sup> It is stressed, however, that the disclosure in the specification should be drafted carefully to provide sufficient support for the given wording or term, otherwise it will not be accepted.<sup>152</sup>

## 2. Vectors

A vector can be defined by specifying the base sequence of DNA, the DNA cleavage map,<sup>153</sup> the molecular weight, the number of base pairs, the source, the process of preparation, the function, the property.<sup>154</sup> Additionally, if the biological material is new, it is preferable that the vector be deposited in an International Depositary Authority according to the rules established in the Budapest Treaty, and defined by its accession number.<sup>155</sup>

## VI. INTERPRETATION OF PATENT CLAIMS

A clear understanding of the rules that permeate the industrial property system—particularly the violation of patent rights—is important, even for companies that do not normally patent their products or processes.<sup>156</sup> The development of a product can become a living nightmare, notably upon entrance into the marketplace, if it is discovered that the product cannot be marketed

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<sup>150</sup> See Allison Morse, *Searching for the Holy Grail: The Human Genome Project and Its Implications*, 13 J.L. & HEALTH 219, 226–27 (1999).

<sup>151</sup> See M. Henry Heines, *Catching Your Breadth*, INTELL. PROP. MAG., Feb. 1997 (stating “the value of a patent is often directly related to the breadth of its claims . . . , it is generally true that the shorter the claim the fewer the limitation and the broader the scope of infringing activity”), available at LEXIS, Patent Library, Ipmag File.

<sup>152</sup> 35 U.S.C. § 112 (2000) (discussing specification in patents).

<sup>153</sup> See Lisa L. Elseview, Recent Development, *Schendel v. Curtis: DNA Standards Misapplied to Fusion Protein Patents*, 4 J. INTELL. PROP. L. 353, 376–77 (1997) (discussing vectors, DNA sequences, and fusion indicating the relative location and distance of the cleavage sites).

<sup>154</sup> See *id.* at 366–68.

<sup>155</sup> See Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, Apr. 28, 1977, art. 2., available at <http://www.wipo.int/clea/docs/en/wo/wo002en.htm> (last visited Oct. 30, 2002).

<sup>156</sup> See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 109, 110–11 (2001) (noting that the lack of patent law knowledge impedes innovation, vastly affecting the smaller companies trying to attract investors).

because it is the subject of a patent held by a third party.<sup>157</sup> The picture worsens further if a company inadvertently places a product on the market or uses a process that is protected by a patent.<sup>158</sup> Conversely, at the time of filing a patent application the applicant should have an understanding of the protection he/she wishes to receive and what this protection means.<sup>159</sup> This will ensure that the property is protected from third parties, and to guarantee the appropriate financial return from exploiting the patent.<sup>160</sup> Such knowledge allows for an evaluation to be made of the impact of the original claim's structure and the potential modifications to be made at the behest of the examiner on the capacity to gain profits from the patent when it is eventually granted.<sup>161</sup> Therefore, the commercial value of a patent is not only measured by the potential of the innovating company to exploit the technology—or to seek partners interested in so doing—but also in part by the scope of the claims.<sup>162</sup>

As a general rule, in order to ascertain whether a patent has been violated, it must be verified if the product or process accused of infringement possesses all the characteristics of one or all of the independent claims in the patent.<sup>163</sup> It is frequently held that the addition of characteristics to the claimed invention does not disprove a violation, regardless if these additional characteristics are themselves known or new, even if inventive.<sup>164</sup> The interpretation of a claim is based on determining the legal meaning of the terms of the claim, attained by an interpretation based on the patent specifications.<sup>165</sup> This can also be done by accessing other information in the state of the art, the file history, and from their over-

<sup>157</sup> See Piatnicia, *supra* note 120, at 384-85.

<sup>158</sup> *Id.*

<sup>159</sup> See Alan S. Gutterman, *A Legal Due Diligence Framework for Inbound Transfers of Foreign Technology Rights*, 24 INT'L LAW. 976, 977 (1990).

<sup>160</sup> *Id.*

<sup>161</sup> See Ko, *supra* note 48, at 780.

<sup>162</sup> *Id.* at 778.

<sup>163</sup> See *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1577 (Fed. Cir. 1989) (stating that "[t]o establish infringement of a patent, every limitation set forth in a claim must be found in an accused product or process exactly or by a substantial equivalent").

<sup>164</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1838 (2002) (discussing how a patentee may rebut the presumption that estoppel bars a claim of equivalence). "The patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id.* at 1842.

<sup>165</sup> See *Abtox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed. Cir. 1997).



all significance in the technical field in question.<sup>166</sup> A search for the words to be used in the claims in technical dictionaries or books by expert authors is also of great help.<sup>167</sup>

When determining the scope of a claim, the starting point is considered to be that violation of a patent can basically occur in one of the two following ways: (i) a literal infringement or (ii) an infringement by equivalence.<sup>168</sup> A literal infringement occurs when each element of the infringing product coincides with the definition contained in the claim.<sup>169</sup> In this case, it may be necessary to interpret the significance or scope of a specific expression in the claim, but once the interpretation and scope of the expression occurs, the correspondence with the element in the violating product is immediate.<sup>170</sup> Infringement by equivalence—one of the forms of non-literal infringement—occurs when an element of the infringing product does not correspond directly to the element of the claim, but constitutes a functional technical equivalent to it.<sup>171</sup> The admission of this type of violation is important in preventing the unfair loss of protection through inadequate drafting of patent claims, and also in preventing unlicensed third parties from unduly benefiting from such a patent.<sup>172</sup>

Therefore, the basic legal notion of equivalence is that a device may fall within the ambit of a patent, even though it does not fulfill the language of the patent claim completely.<sup>173</sup> Technically speaking, in case the allegedly infringing device does not include

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<sup>166</sup> See *Vitronics Corp. v Conceptronic, Inc.*, 90 F.3d 1576, 1582–83 (Fed. Cir. 1996) (stating the steps taken when interpreting a claim, such as analyzing the file history on prior art).

<sup>167</sup> See *id.* at 1584 n.6.

<sup>168</sup> See Sean T. Moorhead, Note, *The Doctrine of Equivalents: Rarely Actionable Non-Literal Infringement or the Second Prong of Patent Infringement Charges?*, 53 OHIO ST. L.J. 1421, 1448 (1992).

<sup>169</sup> See *General Mills, Inc. v Hunt-Wesson, Inc.*, 103 F.3d 978, 981 (Fed. Cir. 1997). “Literal infringement requires that every limitation of the patent claim be found in the accused infringing device.” *Id.*

<sup>170</sup> See KENNETH J. BURCHFIELD, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 239–40 (1995). “[T]he proper scope of the claim must be ascertained, without reference to the accused product or device, by the preliminary step of ‘claim construction.’ Only after the meaning of the claim terminology is ascertained as a matter of law is the claim compared with the accused product or process.” *Id.*

<sup>171</sup> See *General Mills*, 103 F.3d at 984.

<sup>172</sup> See Noreen Krall & Celeste B. Filoia, *The Doctrine of Equivalents: An Analysis of the Festo Decision*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 373, 383 (2001) (commenting that patent attorneys must be careful to avoid both obtaining inadequate protection and drafting claims too narrowly).

<sup>173</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1838 (2002) (“The doctrine of equivalents allow the patentee to claim those

all the elements that constitute the invention according to the claim, but substitutes one or more of those elements by different means it may perform the same function in the over-all mechanism.<sup>174</sup> One tendency of this doctrine is towards the basic question of (known) interchangeability, that is a person skilled in the art trying to solve the problem underlying the invention could have arrived at the substituted means without inventive effort of his own.<sup>175</sup> If the variant and its similarity in function had been obvious to him, there would still be infringement.<sup>176</sup>

#### A. *The Japanese Supreme Court's decision in Sliding Ball Spline*

In 1998, the Japanese Supreme Court decided the *Sliding Ball Spline* case and formally approved the Doctrine of Equivalents.<sup>177</sup> The decision lists five prerequisites for a judgment in favor of the patentee: (1) the substituted element does not pertain to an essential portion of the patented invention;<sup>178</sup> (2) the allegedly infringing device achieves the object of the patented invention and exhibits the same function and effects;<sup>179</sup> (3) a person skilled in the art could have readily conceived the interchangeability of the alleged infringement at the date of infringement;<sup>180</sup> (4) the accused device was not an obvious variant of the state of the art known at the time of the patent application;<sup>181</sup> (5) the accused device does not fall foul of the file wrapper estoppel considerations, insuring that the applicant did not intentionally remove it from the scope of protection during prosecution in order to avoid a prior art objection.<sup>182</sup> This test includes policy considerations that may be qualified as common ground in claim construction and

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insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes.”)

<sup>174</sup> See *id.* at 1835.

<sup>175</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 617 (Fed. Cir. 2000) (Michel, J., concurring in part, dissenting in part) (indicating that to avoid this infringement, applicants would need to claim every analog that functions equivalently to the claimed protein).

<sup>176</sup> See *id.*

<sup>177</sup> *Tsubakimoto Seiko Co. v. THK Co.*, Case No. 1994 (o) 1083 (Feb. 24, 1998), translated in *PATENTS & LICENSING* (1998) (noting that the decision was rendered fourteen years after the plaintiff commenced litigation in the Tokyo District Court), available at <http://www.okuyama.com/doi.doc> (last visited Oct. 30, 2002).

<sup>178</sup> See *id.*

<sup>179</sup> See *id.*

<sup>180</sup> See *id.*

<sup>181</sup> See *id.*

<sup>182</sup> See *id.*

that can be traced back to the already stated main policy objective of balancing the opposite interests involved.<sup>183</sup>

*B. The United States Supreme Court in Festo Corp.*

However, the patent applicant must bear in mind that every claim element that is amended during prosecution with the aim of overruling a rejection related to patentability—obviousness or insufficiency of disclosure—may completely bar the use of the doctrine of equivalents on the amended claim element.<sup>184</sup> In the United States, the Federal Circuit's recent decision in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*<sup>185</sup> has made an immediate impact on all pending applications and the majority of valid patents issued.<sup>186</sup> The holding has severely limited the application of the doctrine of equivalents to nearly every claim element that has been amended during the prosecution of the patent application.<sup>187</sup> Specifically, the court held that when a patent applicant amends a claim element during the prosecution of the patent application, which in turn narrows the scope of the claim, the doctrine of equivalents is not available for the element unless the patentee can prove wrong the assumption that the amendment was made for a reason unrelated to patentability.<sup>188</sup>

The case, one of the most important patent cases in decades, went to the United States Supreme Court and on May 28, 2002, the Supreme Court reaffirmed a central tenet of patent law and restored the inherent value of well over a million patents.<sup>189</sup> In *Festo*, the Federal Circuit mandated that virtually any change in a patent claim would invoke prosecution history estoppel concerning the amended element.<sup>190</sup> This complete bar approach was strongly criticized by the Supreme Court as too rigid and not in accordance with long-established precedent.<sup>191</sup> Although a complete bar has the merits of providing certainty as to when estoppel applies and conserving judicial resources on this issue, the

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<sup>183</sup> See *supra* note 101 and accompanying text.

<sup>184</sup> See *infra* notes 182–91 and accompanying text.

<sup>185</sup> 234 F.3d 558 (Fed. Cir. 2000).

<sup>186</sup> See Alan P. Klien, *The Doctrine of Equivalents: Where it is Now, What it is*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 514, 514 (2001).

<sup>187</sup> See *id.*

<sup>188</sup> See *Festo Corp.*, 234 F.3d at 567–68.

<sup>189</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1843 (2002).

<sup>190</sup> See *Festo Corp.*, 234 F.3d at 566.

<sup>191</sup> See *Festo Corp.*, 122 S. Ct. at 1840–41.

Supreme Court considered the trade-off too high and violative of the legitimate expectations of inventors, past and present, in seeking patent protection.<sup>192</sup> Instead, the Court favored a return to a "flexible bar" approach, where estoppel may or may not apply depending on the reasons for the claim modifications and the understanding of those making the modifications.<sup>193</sup> The Court held that the burden of estoppel presumption can be overcome when:

The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.<sup>194</sup>

Now, with a flexible bar, patentees can raise the doctrine of equivalents against infringers even where claims have been amended so long as the particular equivalents at issue were not conceded to obtain the patent. They are not guaranteed victory, but patentees have the chance again, on a case-by-case basis, to make their arguments.

## VII. CONCLUSION

If a valid patent is to be obtained, it is necessary to determine the limits between the invention and the technical state of the art. Meanwhile, if a competitor can compete with the patent holder for the patented product without violating the rights over the object defined in the claims, then the exclusive rights of the patent holder lose all meaning. We have now reached a point in which patent offices and courts of law around the world are about to render decisions of crucial importance charting the direction of one of mankind's scientifically most important and legally most challenging fields of technology. Furthermore, patent practitioners should follow the following points during preparation of applications: (i) make sure there is support for the claims: track the language used in the claim back to the specific description to ensure the same terminology is used; (ii) check whether the term used has an established meaning in the art and whether that

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<sup>192</sup> *Id.*

<sup>193</sup> *Id.* at 1842.

<sup>194</sup> *Id.*

meaning is appropriate in the particular circumstances in which it is to be used; (iii) avoid amendment during prosecution; and (iv) describe multiple embodiments wherever possible.

Concerning specific issues relating to natural products, we consider it healthy for there to be closer cooperation between developed nations that are rich in technology and a specialized workforce, and the developing world that has an abundance of genetic resources and traditional knowledge. We consider this to be true even if the criteria and degree of interaction requires greater discussion so the needs and wishes of all involved, including local communities, are reflected. Without a doubt, a balance must be sought between sharing the benefits available and technology transfer. Within this context, it is important that we recognize the need to invest in science and technology in Brazil, with closer public and private interaction. It is equally important to support the expansion of a strong patent system that can assure the academic and business world adequate protection for the results of their investments in research and development. In so doing, great challenges will have to be overcome: the lack of any national system for innovation, a shortage of courts and judges training in judging patent infringement suits, a shortage of patent examiners at the Brazilian Industrial Property Office, and the need for much closer interaction between the realms of academia and business.