

Summer 1998

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J. Michael Warner

Han Xiaoqing

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### Recommended Citation

J. Michael Warner, The Chinese System of Administrative Protection for Pharmaceuticals, 31 J. Marshall L. Rev. 1165 (1998)

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# THE CHINESE SYSTEM OF ADMINISTRATIVE PROTECTION FOR PHARMACEUTICALS

J. MICHAEL WARNER\* AND HAN XIAOQING\*\*

## I. INTRODUCTION

Intellectual property law and its enforcement in the People's Republic of China has been an important topic of discussion for many years.<sup>1</sup> There are several reasons for this interest. China is emerging as a major force in the world economy. China has the world's fastest-growing economy, and it is also the world's eleventh largest trading nation<sup>2</sup> with 1994 total trade valued at over U.S. \$235 billion.<sup>3</sup> China's economy is becoming increasingly interdependent with those of other nations.<sup>4</sup> Not only is China exerting a greater influence on economies outside its borders,<sup>5</sup> but busi-

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\* Assistant General Counsel, Monsanto Company Law Department - IP; Ph.D. Indiana University (1982); J.D. St. Louis University (1998); B.S. Centenary College of Louisiana (1977).

\*\* Deputy Director, Asia and Pacific Division of the International Cooperation Department of the Patent Office of the People's Republic of China (retired); LL.M. The John Marshall Law School (1997); M.I.P. Franklin Pierce Law Center (1987); B.A. Tsinghua University (1977).

This article is based on the authors' Independent Study at The John Marshall Law School. The authors would like to thank Dean R. Gilbert Johnston of The John Marshall Law School for his insightful comments on the Independent Study.

1. For recent discussions and divergent views, see, for example, Qiao Dexi, *A Survey of Intellectual Property Issues in China-U.S. Trade Negotiations under the Special 301 Provisions*, 2 PAC. RIM L. & POL'Y J. 259 (1993); Laurence P. Harrington, *Recent Amendments to China's Patent Law: The Emperor's New Clothes*, 17 B.C. INT'L & COMP. L. REV. 337 (1994); Geoffrey T. Willard, *An Examination of China's Emerging Intellectual Property Regime: Historical Underpinnings, the Current System and Prospects for the Future*, 6 IND. INT'L & COMP. L. REV. 411 (1996).

2. *For Richer or Poorer . . .*, NEWSWEEK, May 19, 1997, at 41.

3. Ge Liu and Alexander Lourie, *International Commercial Arbitration in China: History, New Developments, and Current Practice*, 28 J. MARSHALL L. REV. 539 n.1 (1995). Compare with the total trade in 1993 which amounted to U.S. \$165 billion. Bing Wang, *China's New Foreign Trade Law: Analysis and Implications for China's GATT Bid*, 28 J. MARSHALL L. REV. 495 (1995).

4. *An Embassy in Search of a State*, 22 BUS. CHINA, Apr. 15, 1996, at 6 [hereinafter *Embassy*].

5. Alasdair Forbes, *Asia's Drive to Open Markets*, 32 ASIAN BUS. 10

ness organizations from other nations are increasingly seeking inroads into Chinese markets.<sup>6</sup>

A well-developed, understandable, and enforceable intellectual property system is considered by many foreign investors to be a *sine qua non* for financial involvement in China.<sup>7</sup> The government of China has come to recognize that investment in China and participation in a world economy require a strong set of laws governing intellectual property:

It is the Chinese government's view that the intellectual property protection system plays a significant role in promoting progress in science and technology, enriching culture and developing the economy. It functions both as an important institution ensuring the normal running of the socialist market economy, and as one of the basic environments and conditions for conducting international exchange and cooperation in science, technology, economy and culture.<sup>8</sup>

One way the Chinese government has sought to encourage international investment is through the institution of modern intellectual property laws. Dr. Gao Lulin, Director General of the Chinese Patent Office has stated, "The final goal of the patent system is to encourage proliferation of investment in research work and make better economic benefits for the country."<sup>9</sup> During the period between 1990-1996, China granted 13,153 invention patents to domestic applicants based on 89,053 applications. In contrast, during the same period China granted 19,427 invention patents to foreign applicants based on 79,691 applications.<sup>10</sup> As a percent of activity, participation by foreign applicants is a substantial factor in the operations of the Chinese Patent Office.

The purpose of this article is to examine an aspect of Chinese intellectual property law called administrative protection (also known as "pipeline protection").<sup>11</sup> Section II of this article briefly outlines the historical setting of administrative protection, including the development of an area in Chinese patent law which for a

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(1996); *Embassy*, *supra* note 4, at 6.

6. James Leung, *Issue Paves Way for Miles Ahead*, 32 ASIAN BUS. 10 (1996).

7. *Foreign Investment: Not Quite So Sparkling China*, THE ECONOMIST, Mar. 1, 1997, at 38.

8. *China: White Paper - 'Intellectual Property Protection in China'*, BBC MONITORING SERVICE: FAR EAST, June 20, 1994 [hereinafter *White Paper*] (released by the information office of China's State Council, Beijing, June 16, 1994).

9. Gao Lulin, *China Makes Much Progress on Patent Protection*, CHINA DAILY, Apr. 1, 1995, at 41.

10. Patent Office of the People's Republic of China, 1996 Ann. Rep. 70 & 72.

11. *China's Revised Patent Law Offers Better Protection*, ASIAN ECON. NEWS, Oct. 5, 1992; *Thailand: Patent Protection Casts Pall Over Health Services*, BANGKOK POST, July 17, 1993.

period left "pharmaceutical products and substances obtained by means of a chemical process"<sup>12</sup> without a proprietary position in China. Section III examines the underpinnings of administrative protection negotiated between the United States and China as a stop-gap measure to provide intellectual property protection to certain narrow, yet important, fields of chemical inventions. In Section IV, the article presents and analyzes the regulations and rules promulgated for administrative protection for pharmaceuticals. Section V outlines a hypothetical application of pharmaceutical administrative protection and offers suggestions for further developments in this field of law. Section VI presents the conclusions.

The authors of this paper frequently use the term "compound *per se*." This phrase is a term of art in U.S. patent law and means a specific, identifiable, and reproducible chemical substance, the molecules of which consist of the combination of two or more unlike atoms, and the constituents of which cannot be separated by physical means.<sup>13</sup> A compound *per se* can be characterized by a specific molecular structure. For example, the analgesic acetylsalicylic acid is a compound *per se*.

## II. HISTORICAL SETTING

Although Chinese intellectual property law can be traced back at least three millennia,<sup>14</sup> patent laws similar to those known in the United States and in Europe have developed in China only since the late 1970's.<sup>15</sup> In June of 1980, China became a member of the World Intellectual Property Organization, a specialized agency of the United Nations charged with promoting intellectual property protection on a world-wide basis.<sup>16</sup> In 1980, even before the promulgation of a patent law, China founded the Patent Office of the People's Republic of China (CPO).<sup>17</sup> These and other steps paved the way for the passage of the Patent Law of the People's Republic of China by the National People's Congress on March 12, 1984.<sup>18</sup> On January 1, 1994, China became a signatory nation to the Patent Cooperation Treaty, an instrument which establishes a

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12. Patent Law of the People's Republic of China, art. 25 (1984) (amended 1992).

13. HACKH'S CHEMICAL DICTIONARY 218 (Julius Grant ed., McGraw-Hill Book 3d ed. 1946); DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 337 (Daniel N. Lapedes ed., McGraw-Hill Book Co. 2d ed. 1978).

14. Geoffrey T. Willard, *An Examination of China's Emerging Intellectual Property Regime: Historical Underpinnings, the Current System and Prospects for the Future*, 6 IND. INT'L & COMP. L. REV. 411, 413 (1996).

15. *White Paper*, *supra* note 8, at 3.

16. *Id.*

17. *Id.*

18. Patent Law of the People's Republic of China, adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress on Mar. 12, 1984.

mechanism for filing parallel patent applications on the same invention in several countries.<sup>19</sup>

Beginning on April 1, 1985, Chinese Patent Law provided protection for a variety of inventions.<sup>20</sup> The law spelled out three requirements for patentability: "Any invention or utility model for which patent rights may be granted must possess novelty, inventiveness and practical applicability."<sup>21</sup> However, the law expressly excluded from patent protection the following categories: scientific discoveries; rules and methods for mental activities; methods for the diagnosis or for the treatment of diseases; food, beverages and flavorings; pharmaceutical products and substances obtained by means of a chemical process; animal and plant varieties; and substances obtained by means of nuclear transformation.<sup>22</sup> The exclusion of pharmaceutical products and substances obtained by means of a chemical process meant that certain classes of chemical inventions could not be protected under the 1984 Patent Law.<sup>23</sup> This exclusion extended to, *inter alia*, new pharmaceutical compounds *per se*,<sup>24</sup> compositions or mixtures of pharmaceutical products,<sup>25</sup> and agricultural compounds *per se*.<sup>26</sup> Treatment of patent applications for new uses of known pharmaceutical compounds was inconsistent. Some Chinese examiners routinely rejected such new use patent claims,<sup>27</sup> while other Chinese examiners would allow them if other requirements for patentability were also met.<sup>28</sup>

However, in 1992, the Patent Law of the People's Republic of China underwent its first revision.<sup>29</sup> Among other changes, Article 25 was modified to omit pharmaceutical products and substances obtained by means of a chemical process from the express list of

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19. Qiao Dexi, *On the Second Revision of the Chinese Patent Law*, CHINA PAT. & TRADEMARKS, July 1996, at 6.

20. Patent Law of the People's Republic of China, art. 69 (1984).

21. *Id.* art. 22. For comparison, the United States requirements for patentability of an invention are novelty, non-obviousness, and utility. 35 U.S.C. §§ 101-03 (1997).

22. Patent Law of the People's Republic of China, art. 25 (1984).

23. Li Luoying, *Answers to Questions Concerning Patent Protection for Chemical Inventions in China*, CHINA PAT. & TRADEMARKS, Apr. 1989, at 23.

24. *Id.* at 23.

25. *Id.* at 23.

26. *Id.* at 24. Interestingly, in contrast to pharmaceuticals, new uses for known agricultural compounds and agricultural compositions could obtain patent protection under the 1984 law. *Id.*

27. *Id.*

28. Telephone Interview with Lu Suhua, Director General of Chemical Examination Department, Chinese Patent Office (Aug. 5, 1997).

29. Patent Law of the People's Republic of China, amended by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 27th Session of the Standing Committee of the Seventh National People's Congress on September 4, 1992. In 1996 the Patent Law of the People's Republic of China underwent a second revision, the specifics of which are not relevant to the scope of this paper.

inventions for which no patent right shall be granted.<sup>30</sup> Because of this amendment, new pharmaceutical compounds *per se*, new uses for known pharmaceutical compounds, pharmaceutical compositions, and agricultural compounds *per se* were eligible for patent grants beginning January 1, 1993.<sup>31</sup>

As a result of these developments, a patent law existed in China during the period from April 1, 1985 to January 1, 1993, but it provided little protection for inventors of pharmaceutical or agricultural products. Other provisions of the Chinese Patent Law (both preceding and following the 1992 revisions) are very similar to those in the United States or Europe. As in the United States and Europe, Chinese patent protection for inventions under the current law extends for twenty years from the date of filing a patent application.<sup>32</sup> A Chinese patent is granted to the first person to file a patent application for a qualifying invention, just like the European system.<sup>33</sup>

Many parties in the United States expressed concern over inadequate protection of chemical inventions during the period from 1985 to 1993.<sup>34</sup> In May 1991, the United States Trade Representative (USTR) launched an investigation pursuant to the United States Omnibus Trade and Competitiveness Act of 1988,<sup>35</sup> which requires an investigation of "whether any act, policy, or practice described in Section 301 of the Trade Act exists and, if that determination is affirmative, determine what action, if any, to take under Section 301 of the Trade Act."<sup>36</sup> In Section 301 of the Trade Act (known as "Special 301"),<sup>37</sup> the USTR must undertake the mandatory investigation "[i]f the United States Trade Representative determines under Section 304(a)(1)<sup>38</sup> that an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce . . . ."<sup>39</sup> Depending upon the result of the investigation, the USTR may, at the direction of the President, take a variety of actions, including suspension or withdrawal of benefits of trade agreement concessions and

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30. *Id.* art. 25. Another modification to art. 25 was to omit food, beverages and flavorings from the express list of inventions for which no patent right shall be granted. *Id.*

31. *Id.* art. 69.

32. *Id.* art. 45. Under the 1984 Patent Law, the term of an invention patent extended 15 years from the date of filing of the patent application. *Id.*

33. *Id.* art. 9. In the United States patents are awarded on the basis of first-to-invent. 35 U.S.C. § 102 (1997).

34. Dexi, *supra* note 1, at 277.

35. 19 U.S.C. § 2411(a)(1) (1996).

36. Initiation of Section 302 Investigation and Request for Public Comment: Intellectual Property Laws and Practices of the People's Republic of China, 56 Fed. Reg. 24878 (1991).

37. Dexi, *supra* note 1, at 273.

38. 19 U.S.C. § 2414(a)(1) (1996).

39. 19 U.S.C. § 2411(b)(1) (1996).

imposition of duties or other import restrictions on the goods of the foreign country being investigated.<sup>40</sup>

However, the USTR is under no obligation to take such action if he finds that the foreign country "is taking satisfactory measures to grant the rights of the United States under a trade agreement [or] the foreign country has agreed to eliminate or phase out the act, policy, or practice, or agreed to an imminent solution to the burden or restriction . . . ."<sup>41</sup> The USTR is authorized to enter into binding agreements with the foreign country for the purpose of phasing out the disputed act, policy, or practice.<sup>42</sup> The Trade Act gave the USTR considerable leverage for negotiations with China over intellectual property rights.

### III. NEGOTIATED UNDERPINNINGS OF ADMINISTRATIVE PROTECTION

Trade between China and the United States has grown tremendously over recent decades.<sup>43</sup> In parallel with this growth, disputes have arisen between individuals or businesses in the two countries over the nature and extent of intellectual property rights. Of particular contention was the absence of protections for chemical inventions from the 1985 Chinese Patent Law.<sup>44</sup> As a result of extensive negotiations on this issue, the United States and China in 1992 entered into an agreement in the form of a Memorandum of Understanding<sup>45</sup> (1992 Memorandum). In Article 1 of the 1992 Memorandum, China agreed to extend patent coverage to all chemical inventions, including those of pharmaceutical and agricultural chemicals, products, and processes.<sup>46</sup> In fact, under the 1992 patent law revisions, "patents may be granted to all types of technological inventions, whether new products or new techniques, including pharmaceutical products and substances obtained by means of a chemical process, foods, beverages, and flavorings."<sup>47</sup> China also agreed to modify the term of invention patent protection<sup>48</sup> from fifteen to twenty years from the date of filing of the

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40. *Id.* § 2411(c)(1).

41. *Id.* § 2411(a)(2)(B).

42. *Id.* § 2411(c)(1)(D).

43. Dexi, *supra* note 1, at 262.

44. *Id.* at 277.

45. *People's Republic of China-United States of America: Memorandum of Understanding on the Protection of Intellectual Property*, 34 I.L.M. 676 (1995) [hereinafter *Memorandum*]. In 1995 China and the U.S. concluded a second Memorandum of Understanding, also dealing with intellectual property rights, but covering topics outside the scope of this paper. *Id.*

46. *Id.* at 677.

47. *White Paper*, *supra* note 8, at 6.

48. Chinese patent law recognizes three kinds of patents: invention, utility model, and design patents. Invention and utility model patents must meet the requirements of novelty, inventiveness, and practical applicability. Patent Law of the People's Republic of China, art. 22 (1984) (amended Sep. 4, 1992).

patent application.<sup>49</sup> Additional provisions dealt with copyright,<sup>50</sup> unfair competition,<sup>51</sup> and trade secrets issues.<sup>52</sup>

In Article 2 of the 1992 Memorandum, China agreed to "provide administrative protection to U.S. pharmaceutical and agricultural chemical product inventions . . ."<sup>53</sup> This administrative protection was meant to provide retroactive patent-like protection to certain U.S. pharmaceutical and agricultural chemical product inventions which were denied patent protection under the 1984 Patent Law.<sup>54</sup>

The scope of inventions to be given retroactive protection under administrative protection was considerably narrower than the scope under the negotiated revisions to the patent law. The Chinese government agreed to provide administrative protection to U.S. pharmaceutical and agricultural chemical product inventions which meet certain substantive requirements. The protection could apply if the pharmaceutical and agricultural chemical product inventions:

- (i) were not subject to protection by exclusive rights prior to the amendment of current Chinese laws;
- (ii) are subject to exclusive right to prohibit others from making, using or selling it in the United States which are granted after January 1, 1986 and before January 1, 1993;
- (iii) have not been marketed in China.<sup>55</sup>

In addition, to obtain administrative protection a U.S. "owner of the exclusive right" to the chemical product would have to provide competent Chinese authorities with a set of documents.<sup>56</sup> The prescribed documents in effect present a set of procedural requirements. The documentation includes:

- (1) a copy of the certificate issued by the competent authorities of

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An invention patent is distinguished from a utility model patent in that the former requires an examination, *id.* art. 34, and has a term of protection extending 20 years from the date of filing of the application. *Id.* art. 45. The latter does not have an examination requirement and its term of protection extends ten years from the date of filing of the application. *Id.* A design patent may be granted for any design which has not been publicly disclosed or publicly used. *Id.* art. 23. The term of protection for a design patent extends ten years from the date of filing of the application. *Id.* art. 45.

49. *Memorandum, supra* note 45, at 677.

50. *Id.* at 681.

51. *Id.* at 683.

52. *Id.*

53. *Id.* at 679.

54. *U.S., China Reach Trade Agreement, Averting Possible Sanctions*, REUTERS N. AM. WIRE, Jan. 16, 1992; *Memorandum, supra* note 45, at 679.

55. *Memorandum, supra* note 45, at 679-680.

56. *Id.* at 680.



the United States granting such exclusive right;

(2) a copy of the document issued by the competent authorities of the United States for the approval for manufacturing or sale of such product; and

(3) a copy of a contract for the manufacture and/or sale entered into between the owner of the exclusive right and a Chinese legal person (including foreign capital enterprises, joint venture enterprises, or cooperative enterprises) with respect to the manufacture and/or sale of the product in China.<sup>57</sup>

In combination, these substantive and procedural requirements for administrative protection would maintain a narrow scope of protectable inventions in a number of ways. Regarding the substantive requirements, firstly, the invention must not have been the subject of a patent under the 1984 Patent Law. This provision makes sense because it avoids double protection of a single invention. If a single invention is placed under the umbrellas of both a patent and a certificate for administration protection, the duration of the coverage for the two rights may not expire at the same time. Double protection of this nature could extend patent or patent-like protection of an invention beyond the period intended by the law. In the United States, double patenting is a basis for rejecting a patent claim or application<sup>58</sup> or for finding an issued patent or patent claims invalid.<sup>59</sup> A similar provision in the 1992 Memorandum prevents a situation in which an applicant could wait until near the end of the life of a Chinese patent and then apply for administrative protection, potentially extending the proprietary life of the product by several years.

Second, the invention for which administrative protection is sought would have to be the subject in the United States of an exclusive right prohibiting others from making, using, or selling it.<sup>60</sup> The applicant must submit to the Chinese authorities the certificate documenting this right.<sup>61</sup> For practical purposes, this means that the invention must be the subject of a valid U.S. patent. However, the language of this requirement could be important when China enters into similar administrative protection agree-

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57. *Id.*

58. PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 804 (7th ed. rev. July 1996) [hereinafter MPEP].

59. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 U.S.P.Q.2d (BNA) 1839, 1845 (1992) (A process for decaffeination of raw coffee and a process for recovery of caffeine as a by-product of the decaffeination process are held to be patentably distinct process inventions covered by separate patents which have different expiration dates).

60. *Memorandum*, *supra* note 45, at 680.

61. *Id.*

ments with certain other nations. If the agreement simply states that the invention must be the subject of a patent in the foreign nation, the language could lead to some confusion. For example, Belgium issues at least two types of patent documents: a *brevet octroyé* and a *brevet publié*.<sup>62</sup> The former document is simply a certification that a patent application meets certain formal requirements without granting specific rights; the latter document grants a right to prevent others from making, using, or selling the subject invention. The specific language used in the 1992 Memorandum would prevent such confusion because only a *brevet publié* would meet the administrative protection requirements.

Third, the invention must not have been marketed in China.<sup>63</sup> As will be discussed later, the drafters of the Chinese Regulations on Administrative Protection of Pharmaceuticals elaborated this, requiring that the invention must not have been marketed in China prior to the date on which application for administrative protection is made.<sup>64</sup> This requirement is similar to the public use or sale doctrine in the United States wherein patentability of an invention is precluded if it was "in public use or on sale in [the United States], more than one year prior to the date of the application for patent . . ."<sup>65</sup>

Regarding the procedural requirements, the applicant must prove that the invention is patented in the United States by submitting a copy of the U.S. patent certificate.<sup>66</sup>

Next, the applicant must submit documentation proving that the competent authority has approved the chemical product for the manufacture or sale in the United States.<sup>67</sup> Of all the requirements, this has the greatest effect on maintaining a narrow scope for administrative protection. In order to submit the required documentation, the applicant must first have the chemical product approved by the appropriate authority in the United States. In the case of pharmaceuticals, the authority is the Food and Drug Administration (FDA) under the Department of Health and Human Resources.<sup>68</sup> Such registrations must be performed on compounds *per se* and on formulations or dosage forms of the pharmaceuticals.

The research and registration costs to bring a new pharma-

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62. Application of Ekenstam, 118 U.S.P.Q. (BNA) 349, 350 (1958). A transliteration of *brevet octroyé* is "patent granted" and a transliteration of *brevet publié* is "patent published."

63. *Memorandum, supra* note 45, at 680.

64. Regulations on Administrative Protection of Pharmaceuticals, art. 5 (approved by the State Council on December 12, 1992 and promulgated by the State Pharmaceutical Administration on December 19, 1992) (unofficial translation).

65. 35 U.S.C. § 102(b) (1997).

66. *Memorandum, supra* note 45, at 680.

67. *Id.*

68. 21 U.S.C. § 371 (1997).

ceutical product to a market have been estimated to be greater than U.S. \$230 million.<sup>69</sup> Because of the extremely high cost of new pharmaceutical commercialization, drug companies are likely to seek the registration for only a limited number of compounds *per se*. In addition, pharmaceuticals with closely related chemical structures frequently have similar physiological activities and similar markets. It does not make economic or commercial sense to register multiple compounds *per se* within a chemical family if there are no distinct and profitable markets to support those registrations. In contrast, patents in the United States frequently cover entire chemical families. Each chemical family may contain hundreds or even thousands of compounds *per se*.<sup>70</sup> In such cases, the number of FDA-registered compounds *per se* and associated dosage forms which derive from a patent of this nature is considerably smaller than the set of compounds *per se* which are covered by the patent. Since the application for administrative protection requires the documentation of FDA registration, the resulting administrative protection is, in this case, narrower than the corresponding U.S. patent.<sup>71</sup>

The narrow scope of administrative protection was not perceived as a disadvantage by those wishing to obtain intellectual property rights in China. Both the Pharmaceutical Manufacturers' Association and the International Intellectual Property Alliance expressed their support for the agreement.<sup>72</sup>

The final procedural requirement for administrative protection is that the applicant would have to demonstrate to the competent Chinese authorities that the applicant has entered into a contract with a Chinese legal person for the manufacture or sale of the chemical product.<sup>73</sup> The term "legal person" is defined in the General Principles of the Civil Law of the People's Republic of China.<sup>74</sup> An enterprise can qualify as a legal person if it meets the specified criteria. The General Principles take particular notice of Chinese-foreign enterprises:

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69. Susan Randel, *R&D Focuses on New Drugs; Pharmaceutical Research and Development*, CHEMICAL BUS., June 1991, at 43. This figure also includes research and development costs.

70. For an example of a patent which covers a family of chemistry encompassing a large number of compounds *per se*, see U.S. Patent 3,694,446.

71. Sometimes the scope of a patent is very narrow. In fact, a patent could cover only a single compound *per se*. See, for example, U.S. Patent 4,517,359. Administrative protection deriving from such a patent would presumably have scope similar to that of the patent.

72. Michael Chugani, *Deal a Boost for Sino-US Links*, S. CHINA MORNING POST, Jan. 18, 1992.

73. *Memorandum, supra* note 45, at 680.

74. General Principles of the Civil Law of the People's Republic of China, art. 36 (1987) (adopted at the Fourth Session of the Sixth National People's Congress, promulgated by Order No. 37 of the President of the People's Republic of China on April 12, 1986) (unofficial translation).

An enterprise owned by the whole people or under collective ownership shall be qualified as a legal person when it has sufficient funds as stipulated by the state; has articles of association, an organization and premises; has the ability to independently bear civil liability; and has been approved and registered by the competent authority.

A Chinese-foreign equity joint venture, Chinese-foreign contractual joint venture or foreign-capital enterprise established within the People's Republic of China shall be qualified as a legal person in China if it has the qualifications of a legal person and has been approved and registered by the administrative agency for industry and commerce in accordance with the law.<sup>75</sup>

Legal persons mentioned in the 1992 Memorandum as qualifying to enter into the contract required for administrative protection include foreign capital enterprises, joint venture enterprises, and cooperative enterprises.<sup>76</sup> Contracts with these enterprises are governed by a variety of Chinese laws including the Foreign Economic Contract Law of the People's Republic of China on Economic Contracts Involving Foreign Interest<sup>77</sup> and the Law of the People's Republic of China on Joint Venture Using Chinese and Foreign Investment.<sup>78</sup>

In sum, the negotiated requirements for applying for and obtaining administrative protection, as outlined in the 1992 Memorandum, were reasonably clear and were acceptable to the various groups concerned.

China had further obligations under the 1992 Memorandum with respect to application for administrative protection. The competent Chinese authorities were required to promptly examine and approve the application in accordance with appropriate Chinese laws and without applying special rules or additional requirements.<sup>79</sup> Upon approval of the application, the Chinese authorities were to grant a certificate for administrative protection. The grant would be for "the right to manufacture or sell the

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75. *Id.* art. 41.

76. *Memorandum*, *supra* note 45, at 680.

77. Foreign Economic Contract Law of the People's Republic of China on Economic Contracts Involving Foreign Interest (adopted on March 21, 1985 at the 10th Session of the Standing Committee of the 6th National People's Congress).

78. Law of the People's Republic of China on Joint Venture Using Chinese and Foreign Investment (adopted by the Second Session of the Fifth National People's Congress on July 1, 1979 and Promulgated on and Effective as of July 8, 1979). A thorough review of direct investment and joint ventures in China was recently published. See Daniel J. Brink and Xiao Lin Li, *A Legal and Practical Overview of Direct Investment and Joint Ventures in the 'New' China*, 28 J. MARSHALL L. REV. 567 (1995).

79. *Memorandum*, *supra* note 45, at 680.

subject product."<sup>80</sup> This wording is interesting in comparison to the rights granted in a Chinese or U.S. patent. After a Chinese invention patent has been granted, "no entity or individual may, without the authorization of the patentee, exploit the patent, that is, make, use or sell the patented product, or use the patented process for production or business purposes."<sup>81</sup> Similarly, the U.S. patent law states, "whoever without authority makes, uses, offers to sell or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."<sup>82</sup>

In other words, a Chinese or U.S. patent does not grant the right to make, use, or sell an invention; it grants the right to prevent others from making, using, or selling the invention. In contrast, the administrative protection certificate, according to a literal interpretation of the 1992 Memorandum, would grant an affirmative right to make, use, or sell the invention. Without more, the grant of administrative protection as described thus far would have no teeth; it would be a grant of a right to manufacture or sell but without a right to protect the invention from infringement by others. However, the 1992 Memorandum continued:

The competent Chinese authorities will prohibit persons who have not obtained a certificate for administrative protection from manufacturing or selling the subject product during the term of administrative protection.<sup>83</sup>

The prohibition against manufacturing or selling by persons who have not obtained both a certificate and the grant of rights to the certificate holder seems to provide the "protection" part of administrative protection. In fact, if implemented in a literal fashion, the rights granted under administrative protection would be more extensive within the narrow area protected than the rights granted under a patent: the grant described by the 1992 Memorandum would include the right to manufacture or sell as well as the right to prevent others from manufacturing or selling.

The final part of the description of administrative protection in the 1992 Memorandum includes an agreement that the term of the protection would start from the date on which the certificate is granted and would last for seven years and six months.<sup>84</sup> China and the United States agreed that administrative protection would become available on January 1, 1993.<sup>85</sup>

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80. *Id.*

81. Patent Law of the People's Republic of China, art. 11 (1992).

82. 35 U.S.C. § 271(a) (1997).

83. *Memorandum, supra* note 45, at 680.

84. *Id.*

85. *Id.*

#### IV. ADMINISTRATIVE PROTECTION REGULATIONS AND RULES

The 1992 Memorandum of Understanding was signed on January 17, 1992 and China lost little time establishing the internal statutory framework for administrative protection. The State Council approved the Regulations on Administrative Protection of Pharmaceuticals<sup>86</sup> on December 12, 1992 and 18 days later the State Pharmaceutical Administration of the People's Republic of China (SPAC) promulgated the Rules for Implementation of the Regulations on Administrative Protection of Pharmaceuticals.<sup>87</sup> An unofficial translation of the Regulations is provided in Appendix A of this article. Appendix B contains an unofficial translation of the Rules.

##### *The Regulations*

The purpose of the Regulations, outlined in Article 1 of that document, is to encourage economic and technological cooperation with foreign countries and to provide rights under administrative protection for those who possess "the exclusive right of foreign pharmaceuticals."<sup>88</sup> The Regulations are essentially the enabling legislation which allow the establishment of administrative protection as required by the 1992 Memorandum. The exclusive right to which the Regulations refer in this clause is the "exclusive right to prohibit others from making, using or selling [the foreign pharmaceutical] in the United States which was granted after January 1, 1986 and before January 1, 1993,"<sup>89</sup> as described in the 1992 Memorandum.

Although the 1992 Memorandum was an agreement concluded exclusively between the United States and China, the Regulations were written with an eye toward formulating similar treaties or agreements with other countries. Indeed, six months after the execution of the 1992 Memorandum, China and the Commission of the European Communities agreed to extend the principles of administrative protection to the pharmaceutical and agricultural chemical product inventions of the European Community countries.<sup>90</sup> Japan<sup>91</sup> and Switzerland<sup>92</sup> have also reached

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86. Regulations on Administrative Protection of Pharmaceuticals (approved by the State Council on December 12, 1992 and promulgated by the State Pharmaceutical Administration of China on December 19, 1992) [hereinafter the Regulations].

87. Rules for Implementation of the Regulations on Administrative Protection of Pharmaceuticals (promulgated by the State Pharmaceutical Administration of the People's Republic of China on December 30, 1992) [hereinafter the Rules].

88. Regulations, *supra* note 86, art. 1; Lao Zhang, *New Rules on Chemical Rights*, CHINA DAILY, Dec. 31, 1992, at 27.

89. *Memorandum*, *supra* note 45, at 680.

90. Agreed Minutes of a meeting held between Delegations of the Commission of the European Communities and the Government of the People's Re-

agreements with China on administrative protection. To reflect this, Article 3 of the Regulations extends administrative protection to "enterprises and other organizations and individuals from a country or a region, which has concluded a bilateral treaty agreement with [China] . . ."<sup>93</sup> However, the Regulations do not define the word "region."

The Regulations place requirements on pharmaceuticals which are eligible for administrative protection. The requirements closely mirror those outlined in the 1992 Memorandum.<sup>94</sup> First, the pharmaceutical must not be subject to protection under the Chinese Patent law prior to January 1, 1993. Second, the pharmaceutical must be subject to an exclusive right to prohibit others from making, using or selling it in the country to which the applicant belongs. This right must have been granted after January 1, 1986 and before January 1, 1993. Third, the pharmaceutical must not have been marketed in China prior to the administrative protection application filing date.<sup>95</sup>

The substantive and procedural requirements outlined by the Regulations are supplemented by a set of documentation which the applicant must submit with the application for administrative protection. The documentation includes three categories described in the 1992 Memorandum and further includes an application form.<sup>96</sup> The Regulations mandate a Competent Authority for Protection and Distribution of Pharmaceuticals (CAPDP) for the receipt and examination of applications.<sup>97</sup> The CAPDP, in turn, is to designate an organization to act as the applicant's agent during the prosecution of an application.<sup>98</sup> An applicant cannot make his application *pro se*, but must prosecute it through the designated agency. This is in marked contrast to the U.S. patent system in which an applicant can represent himself in two situations. First, if the U.S. patent applicant is also an inventor, he can prosecute the U.S. application *pro se*.<sup>99</sup> In addition, the applicant for a U.S. patent may hire any of a number of licensed patent agents or patent attorneys

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public of China in Beijing on June 29 and 30, 1992; *China Will Grant Some EC Wishes*, CHINA DAILY, June 1, 1992 at 21.

91. *Japan to Seek More Patent Protection from China*, REUTERS FIN. SERVICE, Apr. 28, 1992.

92. Letter from Chang Yongheng, Director, *Foreign Product Registration Division, Department of Medical Device Administration, State Pharmaceutical Administration of China*, to the authors (Aug. 5, 1997).

93. Regulations, *supra* note 86, art. 3.

94. *Id.* art. 5.

95. *Id.*

96. *Id.* art. 8, § 1.

97. *Id.* art. 4. The Rules names the State Pharmaceutical Administration of the People's Republic of China as the CAPDP. Rules, *supra* note 87, art. 2.

98. Regulation, *supra* note 86, art. 7. The Chinese requirement seems to add a level of bureaucracy to the procedure. *Id.*

99. MPEP, *supra* note 58, § 402.01.

to represent him. Second, if the applicant is also a registered patent attorney or patent agent, he can prosecute his own application.<sup>100</sup> The Chinese patent system is between these two positions. An applicant cannot prosecute a Chinese patent application on a *pro se* basis, but may use one of several approved patent agencies. Currently, there are at least nine such approved agencies.

Articles 10 through 12 of the Regulations deal with the examination and approval process. Article 10 requires that the CAPDP shall, within fifteen days of receipt, determine whether the application information is complete and in conformity with Article 8 of the Regulations.<sup>101</sup> Article 11 requires that the CAPDP finish the examination within six months of receiving the full application package. However, the Regulations allow for delays in the examination process under "special circumstances" in which the CAPDP shall "properly prolong the examination time."<sup>102</sup> There is no discussion in the Regulations concerning what issues might constitute special circumstances. The issue of what constitutes special circumstances is important because a clear definition of the term would decrease the likelihood or appearance of arbitrary decision making by CAPDP officials in determining whether administrative protection should be granted.

A seven year-six month term of administrative protection of pharmaceuticals was agreed upon in the 1992 Memorandum and is codified in Article 13. Termination of administrative protection may occur before the end of this period, however, under any of four circumstances detailed in Article 15:

- (1) where the exclusive right in a pharmaceutical has been invalidated or has lost efficacy in the country to which the applicant belongs;
- (2) where the owner of the exclusive right in a pharmaceutical does not pay an annual fee as prescribed;
- (3) where the owner of the exclusive right in a pharmaceutical abandons the administrative protection by a written declaration;
- (4) where the owner of the exclusive right in a pharmaceutical does not apply to ADH for going through the procedures of approval for manufacture or marketing of this pharmaceutical in China within a year from the date on which the certificate for administrative protection of the pharmaceutical is issued.<sup>103</sup>

The point of Article 15(1) is that if a foreign patent becomes invalid in the issuing country, then any pharmaceutical adminis-

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100. *Id.* § 402.

101. Regulations, *supra* note 86, art. 10.

102. *Id.* art. 11.

103. *Id.* art. 15.



trative protection based upon that patent will cease.<sup>104</sup> This makes sense from a policy perspective. Administrative protection is based, in part, on trust placed by the Chinese authorities in the processes by which a foreign country grants valid patents. The Chinese authorities overseeing administrative protection are under no apparent obligation to determine patentability of an invention before granting the protection, and they rely on the foreign country to determine whether the invention deserves protection. If the foreign country determines at some point that the invention is no longer worthy of patent protection under its laws, then it is appropriate for China to cease administrative protection.

Express written abandonment under Article 15 is also a ground for termination of pharmaceutical administrative protection.<sup>105</sup> This means abandonment of the administrative protection itself. Abandonment of the underlying patent would also be the ground for termination of administrative protection, but that topic is covered by Article 15(1) while abandonment of administrative protection falls under Article 15(3).

Another ground on which administrative protection for pharmaceuticals may be terminated is failure to apply to the Ministry of Public Health (called the Administrative Department of Health or ADH under the Regulations) for approval to manufacture and sell the pharmaceutical.<sup>106</sup> This seems to contrast with a literal interpretation of the 1992 Memorandum which states that a certificate for administrative protection "will provide the right to manufacture or sell the subject product."<sup>107</sup> Once administrative protection has been granted to a party, Article 18 of the Regulations prohibits the Ministry of Public Health and local departments of public health from granting to other parties authorization to manufacture or sell the pharmaceutical.<sup>108</sup> Some potential problems which can arise from this separation between issuing certificates of administrative protection and approval of the right to manufacture and sell will be discussed later.

A fourth way in which pharmaceutical administrative protection may cease is if an annual fee required under Article 14 is not paid.<sup>109</sup>

Article 15 describes ways in which administrative protection may terminate because of actions or inaction by the certificate holder or the foreign country. However, a third party may also take direct steps to request the CAPDP to revoke administrative protection. Article 16 of the Regulations states:

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104. *Id.* art. 15(1).

105. *Id.* art. 15(3).

106. *Id.* art. 15(4).

107. *Memorandum*, *supra* note 45, at 680.

108. *Regulations*, *supra* note 86, art. 18.

109. *Id.* art. 15(2).

Where, after the certificate for administrative protection of a pharmaceutical has been issued, any organization or individual thinks that the grant of administrative protection to the subject pharmaceutical is not in conformity with the provisions of these Regulations, it or he may request the CAPDP to revoke the administrative protection of the subject pharmaceutical. Where the owner of the exclusive right of the pharmaceutical is not satisfied with the revocation decision made by the CAPDP, it or he may institute legal proceedings in the People's Court.<sup>110</sup>

The Regulations do not state the grounds on which administrative protection may be revoked by the CAPDP. However, the Rules state that the revocation will be for nonconformity with the requirements of Article 5 of the Regulations.<sup>111</sup> The owner of the invention may appeal the revocation decision to the People's Court. However, the Regulations and the Rules are both silent on the issue of whether the person who requests revocation may appeal the decision. One may request the revocation for any reason with which the requester thinks the grant of pharmaceutical administrative protection does not conform with the Regulations.

An analogous process in the U.S. patent system is the request for reexamination.<sup>112</sup> As with Chinese administrative protection, reexamination may be requested by any person, but it must be based on the existence of prior art which may "have a bearing on the patentability of any claim of a particular patent."<sup>113</sup> If the Commissioner of the U.S. Patent Office determines that there is a substantial new question of the patentability of any claim of the patent, he will issue an order for reexamination of the patent to resolve the question.<sup>114</sup> The reexamination will follow the same procedures as with the initial examination of a patent application and may result in rejection of some or all of the patent claims.<sup>115</sup> If a patent owner is not satisfied with the reexamination result, he may appeal to the Board of Patent Appeals and Interferences.<sup>116</sup> In another similarity to the Chinese administrative protection revocation proceeding, the person requesting the U.S. patent reexamination has no right of appeal.<sup>117</sup>

If someone manufactures or sells a pharmaceutical product without the permission of the person who owns the exclusive right for that product (i.e., is the holder of a certificate of administrative protection), the owner of the right has two remedies he can pursue. He may either seek economic compensation in the People's Court

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110. *Id.* art. 16.

111. Rules, *supra* note 87, art. 21.

112. 35 U.S.C. § 302 (1997).

113. *Id.* § 301.

114. *Id.* § 304.

115. *Id.* § 305.

116. *Id.* § 306.

117. MPEP, *supra* note 58, § 2279.

or he may ask the CAPDP to stop the infringing act.<sup>118</sup>

The term "economic compensation" is not defined in either the Regulations or the Rules. However, the General Principles of the Civil Law of the People's Republic of China (1987) discusses some remedies for infringement of intellectual property rights:

If the rights of authorship (copyrights), patent rights, rights to exclusive use of trademarks, rights of discovery, rights of invention or rights for scientific and technological research achievements of citizens or legal persons are infringed upon by such means as plagiarism, alteration or imitation, they shall have the right to demand that the infringement be stopped, its ill effects be eliminated and the damages be compensated for.<sup>119</sup>

If administrative protection confers "rights of invention or rights for scientific and technological research" on legal persons, then the General Principles seems to provide at least two remedies: injunction (or the right to demand that the infringement be stopped) and damages. In the United States, remedies for patent infringement include injunction, damages, and possibly attorney's fees.<sup>120</sup>

The Regulations give little guidance about civil procedure in administrative protection infringement cases, thereby potentially creating a confusing situation for plaintiffs and defendants. Jurisdiction<sup>121</sup> and venue<sup>122</sup> of patent cases are clearly laid out in United States statutes, giving guidance to all parties.

### *The Rules*

The purpose of the Rules is to implement the Regulations.<sup>123</sup> The Rules are analogous to regulations promulgated in the United States by the administrative agencies to carry out the purposes of the agencies as required by statutes. An unofficial translation of the Rules is presented in Appendix B.

Article 2 of the Rules names the State Pharmaceutical Administration of the People's Republic of China (SPAC) as the competent authority for the production and distribution of pharmaceuticals (CAPDP). The SPAC preexisted the laws on administrative protection. Its function has been to regulate the manufacture, administration, and sale of existing domestic (Chinese) pharmaceuticals. Interestingly, it is the Ministry of Public Health which normally has the responsibility of registering new domestic and foreign pharmaceuticals for manufacture and

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118. Regulations, *supra* note 86, art. 19.

119. General Principles of the Civil Law of the People's Republic of China, art. 118 (1987).

120. 35 U.S.C. §§ 283-285 (1997).

121. 28 U.S.C. § 1338 (1995).

122. *Id.* § 1391.

123. Regulation, *supra* note 86, art. 22.

sale.<sup>124</sup> Because of this, the agency which issues certificates of administrative protection is different from the agency which issues permits for the manufacture and sale of the new pharmaceuticals. This division is in apparent contrast to the agreement in the 1992 Memorandum in which the administrative protection grant links the right to manufacture and sell with the right to exclude others from manufacturing and selling.

The Rules also require the SPAC to establish an Office for Administrative Protection of Pharmaceuticals (OAPP).<sup>125</sup> The OAPP is the department which has direct responsibilities of receiving applications, examining applications, issuing administrative protection certificates, and settling infringement disputes.

As discussed above, Article 7 of the Regulations requires the applicant for pharmaceutical administrative protection to appoint an agency to represent him in prosecuting the application, and that the agency is to be designated by the SPAC. The Rules name only one agency, Huake Pharmaceutical Intellectual Property Consultative Center.<sup>126</sup> Any document or communication relating to administrative protection of pharmaceuticals must be sent to the SPAC through Huake.<sup>127</sup> Also, Huake must be given a power of attorney to represent the applicant.<sup>128</sup> Today, Huake is a state agency which occupies the same building complex as the SPAC.

The Rules define pharmaceuticals as "substances intended for use in the prevention, treatment or diagnosis of human diseases, or intended to effect the purposive regulation of human physiological functions, for which indications, usage and dosage are prescribed."<sup>129</sup> This has led to some minor controversy. The 1992 Memorandum did not define the term "pharmaceuticals" and some applicants for administrative protection have argued that it should include veterinary medicines.<sup>130</sup>

There is a provision in the Rules which is similar to the idea of unity of invention. Unity of invention is a concept under the Patent Cooperation Treaty wherein a patent application must relate to only one invention or to more than one embodiment of the same invention when the technical relationship between the inventions involves "one or more of the same or corresponding spe-

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124. Procedures for the Control of Imported Pharmaceuticals, ch. 1, art. 3 (unofficial translation) (promulgated by the Ministry of Public Health of the People's Republic of China on November 2, 1990), reprinted in CHINA PAT. & TRADEMARKS, April 1991, at 83.

125. Rules, *supra* note 87, art. 2.

126. *Id.* art. 6.

127. *Id.* art. 8.

128. *Id.* art. 11.

129. *Id.* art. 3. The Regulations also define pharmaceuticals in art. 2 as "medicines for human beings." Regulations, *supra* note 86, art. 2.

130. Dexi, *supra* note 1, at 279 n.79.

cial technical features."<sup>131</sup> Under U.S. law, there is a similar requirement that "[t]wo or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention . . . may be claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species . . ."<sup>132</sup> The Rules under the Chinese administrative protection system similarly require that protection for pharmaceuticals is limited to a single invention, e.g., a compound *per se*.<sup>133</sup> However, Article 12 of the Rules precludes protection for families of chemistry. This is more narrow than the unity of invention concepts under the Patent Cooperation Treaty and that under the United States system where families of chemistry can be claimed in a single patent when there is an appropriate relationship of invention in that family. The result is that Chinese administrative protection offers pin-point protection for individual chemical species and is therefore much narrower than protection which could be allowed under a patent.

The Rules provide considerable detail regarding the documents which must be submitted along with the application for pharmaceutical administrative protection. Article 13 outlines seven sets of documents.<sup>134</sup> But Huake and the Pharmaceutical Research and Manufacturers of America (PhRMA) have each issued detailed (and non-identical) lists, which in their experiences of working with administrative protection applicants represent more complete pictures of the needed documentation and which guide the applicant in providing the SPAC with information useful in making a decision on whether to grant a certificate of protection. Huake lists following nine items in the application package.<sup>135</sup>

1. A completed and signed application form.
2. An executed power of attorney.
3. A copy of the specification of the related patent.
4. A copy of the patent certificate.
5. A record of the legal status of the patent or an annual fee record indicating that the patent is still valid.
6. A copy of the marketing approval of the drug granted to the foreign pharmaceutical company.
7. A marketing or manufacturing agreement between the foreign pharmaceutical company and a Chinese enterprise which is qualified for manufacturing or trading of pharmaceuticals in China. The agreement should be notarized by the

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131. Stephen A. Becker, PATENT APPLICATIONS HANDBOOK § 9.09 (1998).

132. 37 C.F.R. § 1.141(a) (1997).

133. Rules, *supra* note 87, art. 12.

134. *Id.* art. 13.

135. Letter from Yu Bo, Huake, *Pharmaceutical Intellectual Property Consultative Center*, to the authors (July 23, 1997).

Chinese public notarization office.

8. The Chinese party to the marketing or manufacturing agreement should provide a qualification and permit, as well as a business license.

9. The appropriate fees for the application and maintenance right. A listing of the fees current as of July 23, 1997 is provided in Appendix C.

The PhRMA list contains most of the same items as the Huake list, but further includes.<sup>136</sup>

10. A certificate issued by the foreign patent office certifying the patent assignment from the patent holder to the assignee.

11. Contract notarization documents.

This combined list is more detailed than that outlined in Article 13 of the Rules. The majority of the Article 13 list is contained in the first item of the combined list (the completed and signed application form). The PhRMA list indicates that the general manager or the chairman of the board of directors of the foreign company applying for pharmaceutical administrative protection should sign the marketing or manufacturing agreement with a Chinese enterprise.<sup>137</sup> If the general manager of the foreign company signs, the package must include a power of attorney in which the chairman of the board authorizes the general manager's signature.

The remaining articles of the Rules describe procedural details such as fees,<sup>138</sup> time limits,<sup>139</sup> and revocation proceedings.<sup>140</sup> A flow chart showing the progression of an application through the administrative protection approval process is shown in Appendix D.

## V. HYPOTHETICAL EXAMPLE

The Regulations and the Rules provide a framework for the creation of pharmaceutical administrative protection. This framework generally conforms to the principles agreed in the 1992 Memorandum which received praises from U.S. and Chinese groups. However, there are some features of the Regulations and Rules and their application which could cause problems for applicants.

The U.S. pharmaceutical industry group, PhRMA, has expressed concerns over the complexity of the overall process in

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136. Letter from Roger A. Brooks, Assistant Vice President, *Japan & Asia-Pacific, International Division, Pharmaceutical Research and Manufacturers of America*, to the authors (June 20, 1997). List numbering by the authors.

137. *Id.*

138. Rules, *supra* note 87, art. 24.

139. *Id.* art. 9.

140. *Id.* art. 23.

China for marketing approval and for the securing of intellectual property rights of pharmaceuticals eligible for administrative protection.

When the Chinese set up the system for the awarding of "Administrative Protection Certificates," they created a small bureaucratic (though not insurmountable) problem by giving the authority for the awarding of these Certificates to the SPAC, while keeping the authority for drug approvals with the Ministry of [Public] Health (MOH). This has led to one very large problem for our member companies, and that is that, while the SPAC may indicate to a company that it is going to receive an Administrative Protection Certificate for a product, the MOH may go ahead and grant a competitor marketing exclusivity for the same product before the PhRMA member company has a chance to utilize its newly-awarded Certificate.<sup>141</sup>

Since the SPAC and the Ministry of Public Health (MPH) are Chinese agencies independent of each other, yet having overlapping responsibilities, it is possible for them to issue inconsistent grants of rights. If the right granted under administrative protection certificate is like a patent right, the certificate holder can prevent others from making or selling his invention. But if the MPH grants an exclusive marketing right for the same pharmaceutical to a party other than the administrative protection certificate holder, then the certificate holder cannot make or sell the invention either. An enforceable administrative certificate would theoretically result in a stalemate.

Nevertheless, the Regulations state that the MPH and local departments of public health shall not authorize others to manufacture or sell pharmaceuticals which have already obtained administrative protection.<sup>142</sup> The health officials are not precluded from authorizing others to manufacture or sell the pharmaceuticals before a party obtains administrative protection. Once the MPH grants manufacturing rights to a competitor, it becomes complicated for the certificate holder to pursue her rights. She may request the SPAC to stop the infringer or she can pursue a remedy in the People's Court.<sup>143</sup> These remedies can lead to drawn-out and expensive procedures in a developing legal system with very little intellectual property case law to draw upon. The costs in time and money could be avoided if the granting of rights to manufacture and sell the pharmaceutical could be coordinated with the granting of administrative protection.

Hypothetical examples help to clarify the issue. Company A

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141. Letter from Roger A. Brooks, Assistant Vice President, *Japan & Asia Pacific, International Division, Pharmaceutical Research and Manufacturers of America*, to Harvey E. Bale 1 (Oct. 21, 1996).

142. Regulations, *supra* note 86, art. 18.

143. *Id.* art. 19.

has applied for a U.S. patent on drug A. Company A is also in the process of seeking approval from the Food and Drug Administration (FDA) to manufacture and market drug A in the United States. Before the patent on drug A is issued, Company B obtains FDA approval for the same drug and has taken steps toward marketing that drug in the United States. When Company A's patent on drug A is issued, Company A has clear recourse in court with ample statutory and case law support to obtain an injunction, damages, and possibly attorney's fees.<sup>144</sup> Company A may pursue these remedies in U.S. district court<sup>145</sup> in the proper venue.<sup>146</sup> The procedures are well understood by the courts and by the attorneys representing the parties because of the long history of patent infringement litigation in the United States. The FDA and the U.S. Patent Office operate independently of each other but there are well-tested mechanisms in place to stop Company B's sales of drug A in the face of a patent issued to Company A even after Company B starts the sales.

However, an analogous situation under Chinese pharmaceutical administrative protection law may lead to a more complicated outcome. In this hypothetical situation, Company A has applied properly for administrative protection of drug A. While the grant of administrative protection is pending Company B obtains approval from the MPH to market drug A. Soon thereafter SPAC grants Company A's application. Compared to the United States, Chinese intellectual property case law and statutory law are not as developed and have not yet undergone the test of time. This is particularly true for the laws around administrative protection, which are even more recent and less tested than the Chinese patent laws. The procedures, jurisdiction, and venue by which Company A can seek injunction or damages are not as clear and well developed as they might have been in the United States, and outcomes at this early stage of Chinese intellectual property law development are much less predictable.

There are at least two ways to ease these issues for the administrative protection applicants. First, the oversight of administrative protection and the granting of approval for the manufacture and sale of new pharmaceuticals could be harmonized into a single organization. If the administrative protection function were in the same departmental structure as the approval function for pharmaceuticals, it may be less likely that contradictory or inconsistent decisions would be made about these two closely linked processes. This would also be more consistent with a literal interpretation of the 1992 Memorandum, wherein China and the

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144. 35 U.S.C. §§ 283-285 (1997).

145. 28 U.S.C. § 1338(a) (1995).

146. *Id.* § 1391(b).



United States agreed that a grant of administrative protection would be for "the right to manufacture or sell the subject invention."<sup>147</sup> A difficulty with this solution, however, is that it would probably take a considerable organizational effort to bring about this harmonization. Because administrative protection is only available for current patents which were issued in a prescribed period of time, the administrative protection framework will cease to exist by a certain date and will be totally supplanted by the Chinese patent system.<sup>148</sup> The large job of harmonizing these functions must be weighed against the limited period of time during which administrative protection will be used.

Second, the Regulations could be modified so that the term of protection begins on the date the application for administrative protection is made. This appears to be a more easily manageable change than harmonization of administrative protection and drug approval processes. The effect of making the term of protection begin on the application date would be the elimination of a situation in which a late-comer Company B could claim manufacturing and sales rights which preexist Company A's administrative protection rights. To compensate for the time lost during the application period, the term of administrative protection could be extended to eight years and six months.

To make this work effectively, Chinese law could also require that if the MPH grants to Company B rights to manufacture and sell drug A and if Company A subsequently is granted administrative protection rights over drug A, then Company B's grant is terminated. This might seem like a harsh penalty if Company B has made expensive investments in capital and time in order to market drug A. However, to be efficient, an enterprise has the responsibility to secure its freedom to operate in light of the intellectual property rights of others. Changing the law in the manner

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147. *Memorandum, supra* note 45, at 680.

148. Administrative protection is based on patents issued in the foreign country after January 1, 1986 and before January 1, 1993. Regulations, *supra* note 86, art. 5, § 2. In the United States, a patent issued between these dates has a 17 year life from the date of issue. 35 U.S.C. § 154 (1980), amended by 35 U.S.C. § 154(a)(2) (1988). In the latest case, a U.S. patent issued on December 31, 1992 would expire December 31, 2009. One of the requirements for administrative protection is that the foreign patent on which it is based is valid and in force. Regulations, *supra* note 86, art. 15, § 1. Therefore all grants of Chinese administrative protection based upon U.S. patents will expire no later than December 31, 2009. Chinese administrative protection will then only be available to those applicants from countries which have patent terms longer than this. The term of European patents issued in the prescribed period is 20 years from the date of application. For the unlikely case in which the European patent application took essentially no time to prosecute, all Chinese administrative protection based on European patents would expire before December 31, 2012. It seems likely that use of the administrative protection system will trail off before that time.

suggested will protect intellectual property rights of Company A and encourage Company B to negotiate with Company A to arrive at an arrangement which is profitable for both parties.

## VI. CONCLUSION

Securing intellectual property rights in China for chemical inventions during the early years of Chinese patent law is a difficult problem. Foreign entities which have invented new pharmaceuticals naturally wish to profit from their inventiveness. If profit can be made, then it will encourage researchers to seek additional inventions and thereby "promote the progress of . . . the useful arts."<sup>149</sup> Along with this, China has an understandable desire to promote domestic research industry to participate in the world market. The laws of administrative protection attempt to give effect to both of these goals.

This article has described details and functions of the Chinese laws which cover administrative protection and how they complement the growing framework of Chinese patent law. The fact that the intellectual property law of China have progressed so rapidly since the early 1980's is a testament to China's strong desire to promote relations and exchange with other countries in the world economy.

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149. U.S. CONST. art. I, § 8, cl. 8.

## Appendix A

REGULATIONS ON ADMINISTRATIVE PROTECTION OF  
PHARMACEUTICALS

(Approved by the State Council on December 12, 1992 and  
Promulgated by the State Pharmaceutical Administration of  
China on December 19, 1992)

[Unofficial translation. In case of discrepancy, the  
original Chinese version shall prevail.]

## CHAPTER I

*General Provisions*

ARTICLE 1. These Regulations are enacted with a view to expanding economic and technological cooperation and exchange with foreign countries, providing administrative protection to the lawful rights and interests of the owners of the exclusive right of foreign pharmaceuticals.

ARTICLE 2. The "pharmaceuticals" as mentioned in these Regulations, refers to medicines for human beings.

ARTICLE 3. Enterprises and other organizations and individuals from a country or a region, which has concluded a bilateral treaty or agreement with the People's Republic of China on administrative protection of pharmaceuticals may apply for administrative protection of pharmaceuticals in accordance with these Regulations.

ARTICLE 4. The competent authority for protection and distribution of pharmaceuticals under the State Council (CAPDP) receives and examines applications for administrative protection of pharmaceuticals, grants administrative protection to the pharmaceuticals which conform with the provisions of these Regulations, and issues the certificates for administrative protection to the applicants.

## CHAPTER II

*Application for Administrative Protection*

ARTICLE 5. A pharmaceutical for which application can be made for administrative protection shall meet the following requirements:

- (1) was not subject to protection by exclusive rights in accordance with the provisions of the Chinese Patent Law prior to January 1, 1993;

(2) is subject to an exclusive right to prohibit others from making, using or selling it in the country to which the applicant belongs, which was granted after January 1, 1986 and before January 1, 1993;

(3) has not been marketed in China prior to the date of filing the application for administrative protection.

ARTICLE 6. The right of applying for administrative protection of pharmaceuticals belongs to the owner of the exclusive right in the pharmaceutical.

ARTICLE 7. Where an owner of the exclusive right in a foreign pharmaceutical applies for administrative protection, he or it shall appoint an agency designated by the CAPDP to act as his or its agent.

ARTICLE 8. An applicant shall provide the following documents both in Chinese and the original language:

(1) an application for administrative protection of the pharmaceutical;

(2) a copy of the certificate issued by the competent authorities of the country to which the applicant belongs granting such exclusive right;

(3) a copy of the document issued by the competent authorities of the country to which the applicant belongs for the approval for manufacture or marketing of such pharmaceutical;

(4) a copy of a contract for the manufacture and/or marketing formally entered into between the applicant and a Chinese enterprise as legal person (including wholly foreign capital enterprises, Chinese-foreign joint venture enterprises or Chinese-foreign cooperative enterprises), which has obtained approval for manufacture or marketing of pharmaceuticals in accordance with the relevant Chinese laws and regulations, with respect to the manufacture and/or marketing of the pharmaceutical in China.

ARTICLE 9. Prior to or after applying for the administrative protection, the owner of the exclusive right in a foreign pharmaceutical shall apply to the administrative department of health under the State Council (ADH) for going through the procedures of approval for manufacture or marketing of the pharmaceutical in China, in accordance with the provisions of The Pharmaceutical Administration Law of the People's Republic of China.

### CHAPTER III

#### *Examination and Approval of Application for Administrative Protection*

ARTICLE 10. Within 15 days from the date of receipt of the application documents for administrative protection, the CAPDP,

upon preliminary examination, shall make the following decisions according to different conditions:

(1) where the application documents are in conformity with the provisions of Article 8 of these Regulations, issue the notice of acceptance and announce it;

(2) where the application documents are not in conformity with the provisions of Article 8 of these Regulations, request the applicant to complement within a definite time, if the time limit for making complement is not met, the application shall be deemed to have not been filed.

ARTICLE 11. The CAPDP shall finish the examination within six months from the date of receipt of the application documents, or from the date of receipt of the application documents stipulated in Article 10(2) of these Regulations. If, under special circumstances, the examination can not be finished within six months, the CAPDP shall promptly notify the applicant, inform the reason and properly prolong the examination time.

After examination, where the application is in conformity with the provisions of these Regulations, administrative protection shall be granted; where the application is not in conformity with the provisions of these Regulations, no administrative protection shall be granted and the reason shall be informed.

ARTICLE 12. Where a pharmaceutical is granted administrative protection, the CAPDP shall issue the certificate for administrative protection and make an announcement.

## CHAPTER VI

### Duration, Cessation, Revocation and Effect of Administrative Protection

ARTICLE 13. The term of administrative protection begins from the date on which the certificate for administrative protection of a pharmaceutical is issued and remains in force for seven years and six months.

ARTICLE 14. The owner of the exclusive right of a foreign pharmaceutical shall pay an annual fee beginning with the year in which the certificate for administrative protection of the pharmaceutical is issued.

ARTICLE 15. In any of the following cases, administrative protection shall cease before the expiration of its duration:

(1) where the exclusive right in a pharmaceutical has been invalidated or has lost efficacy in the country to which the applicant belongs;

(2) where the owner of the exclusive right in a pharmaceutical does not pay an annual fee as prescribed;

(3) where the owner of the exclusive right in a pharmaceutical abandons the administrative protection by a written declaration;

(4) where the owner of the exclusive right in a pharmaceutical does not apply to ADH for going through the procedures of approval for manufacture or marketing of this pharmaceutical in China within a year from the date on which the certificate for administrative protection of the pharmaceutical is issued.

ARTICLE 16. Where, after the certificate for administrative protection of a pharmaceutical has been issued, any organization or individual thinks that the grant of administrative protection to the subject pharmaceutical is not in conformity with the provisions of these Regulations, it or he may request the CAPDP to revoke the administrative protection of the subject pharmaceutical. Where the owner of the exclusive right in the pharmaceutical is not satisfied with the revocation decision made by the CAPDP, it or he may institute legal proceedings in the people's court.

ARTICLE 17. The cessation or revocation of administrative protection of pharmaceuticals shall be announced by the CAPDP.

ARTICLE 18. For pharmaceuticals which have obtained administrative protection, without the authorization of the owners of the exclusive right of the pharmaceuticals, the ADH and the local departments of public health of provinces, autonomous regions or municipalities shall not ratify others to manufacture or sell them.

ARTICLE 19. Where there is any manufacture or marketing of a pharmaceutical with no authorization of the owner of the exclusive right in the pharmaceutical who has obtained administrative protection, the owner of the exclusive right in the pharmaceutical may request the CAPDP to stop the infringing act; if the owner of the exclusive right in the pharmaceutical requests economic compensation, he or it may institute legal proceedings in the people's court.

## CHAPTER V

### *Supplementary Provisions*

ARTICLE 20. The CAPDP shall take measures to keep confidential the materials provided by applicants which the applicants require to be kept confidential.

ARTICLE 21. Any application for administrative protection of pharmaceuticals filed with, and any other relevant proceedings before, the CAPDP shall be subject to the payment of the fee as prescribed.

ARTICLE 22. The rules for the implementation of these Regulations shall be formulated by the CAPDP.

ARTICLE 23. The CAPDP shall be responsible for the interpretation of these Regulations.

ARTICLE 24. These Regulations shall enter into force on January 1, 1993.

## Appendix B

RULES FOR IMPLEMENTATION OF THE REGULATIONS ON  
ADMINISTRATIVE PROTECTION OF PHARMACEUTICALS

(Promulgated by the State Pharmaceutical Administration of  
the People's Republic of China on December 30, 1992.)

[Unofficial translation. In case of discrepancy, the  
original Chinese version shall prevail. Bracketed  
phrases were inserted by the authors of the  
accompanying paper.]

## CHAPTER I

*General Provisions*

ARTICLE 1. These Rules are formulated in accordance with the provisions of Article 22 of the Regulations on Administrative Protection of Pharmaceuticals (Regulations).

ARTICLE 2. The competent authorities for the production and distribution of pharmaceuticals under the State Council (CAPDP), as mentioned in the Regulations, refers to the State Pharmaceutical Administration of the People's Republic of China (SPAC).

The SPAC shall establish an office for administrative protection of pharmaceuticals (OAPP), which shall be responsible of receiving and examining the applications for administrative protection of pharmaceuticals, issuing certificates, making registrations and announcements concerned, and settling infringement disputes.

The administrative department of health under the State Council (ADH), as mentioned in the Regulations, refers to the Ministry of Public Health of the People's Republic of China (MPH).

ARTICLE 3. "Pharmaceuticals," as mentioned in the Regulations, refers to substances intended for use in the prevention, treatment or diagnosis of human diseases, or intended to effect the purposive regulation of human physiological functions, for which indications, usage and dosage are prescribed.

ARTICLE 4. "An owner of the exclusive right in a pharmaceutical," as mentioned in the Regulations, refers to the person or legal entity that possesses the complete rights of manufacturing, using and selling of the pharmaceutical applied for administrative protection.

ARTICLE 5. "Has not been marketed in China," as mentioned in Article 5(3) of the Regulations, refers to [the condition that] the pharmaceutical applied for administrative protection has not been distributed through lawful commercial channels in the pharma-

ceutical markets within China's territory.

ARTICLE 6. The agency, as mentioned in Article 7 of the Regulations, refers to Huake Pharmaceutical Intellectual Property Consultative Center.

ARTICLE 7. Any application for administrative protection of pharmaceuticals filed with the OAPP and any other proceedings concerned shall be prepared in the form prescribed by the SPAC.

ARTICLE 8. Any document concerning administrative protection from the OAPP which needs to be sent to an applicant shall be transmitted by the agency.

ARTICLE 9. The first day of any time limit prescribed in the Regulations or these Rules shall not be counted. Where a time limit is counted according to the period of year or month, the corresponding day of the last month shall be deemed as the expiration date of the limit; if there is no corresponding day in that month, the time limit shall expire on the last day of that month.

If a time limit expires on an official holiday, the time limit shall expire on the first working day after that official holiday.

## CHAPTER II

### *Application for Administrative Protection*

ARTICLE 10. The original language, as mentioned in Article 8 of the Regulations, refers to the official language of the country to which an applicant belongs.

ARTICLE 11. Where an applicant entrusts the agency to handle the application for administrative protection, the parties shall sign a power of attorney which shall indicate the scope of the power entrusted.

When the agency submits the application documents to the OAPP as prescribed in Article 8 of the Regulations and these Rules, it shall submit the power of attorney at the same time.

ARTICLE 12. An application for administrative protection of pharmaceuticals shall be limited to one pharmaceutical.

ARTICLE 13. An application for administrative protection stipulated in Article 8(1) of the Regulations shall include the following:

- (1) the name and address of the applicant;
- (2) the nationality of the applicant;
- (3) where the applicant is an enterprise or an organization, the name of the country or the region in which the headquarters of such enterprise or organization locates;
- (4) the name, chemical structure or formulation in case of pharmaceutical preparation, dosage form, indications, directions for administration, dose and a brief introduction to the processing technology of the pharmaceutical;
- (5) signature or seal of the applicant and the agency;



- (6) list of the application documents;
- (7) other relevant matters needed to be indicated.

ARTICLE 14. The application documents shall be neat and clear and no alteration is allowed. The characters of the documents shall be written from left to right. Drawings shall be made with the aid of a drafting instrument.

The standard scientific and technical terms adopted by the State should be used.

ARTICLE 15. Where, prior to the issuance of the administrative protection certificate, an applicant must withdraw his or its application for administrative protection, he or it should submit a written declaration to the OAPP through the agency, in which the name of the applicant and the name of the pharmaceutical should be indicated.

### CHAPTER III

#### *Examination and Approval of Application for Administration Protection*

ARTICLE 16. Where the documents are submitted to the OAPP under one of the following circumstances, the documents shall be deemed not to be submitted:

- (1) the documents are not presented in the prescribed form or the content is not in conformity with the requirements;
- (2) the documents are not submitted as prescribed.

ARTICLE 17. The OAPP shall finish the examination within the time limit stipulated in Article 11 of the Regulations.

### CHAPTER IV

#### *Duration, Cessation, Revocation and Effect of Administrative Protection*

ARTICLE 18. The issue date of the certificate for administrative protection of a pharmaceutical, as mentioned in Article 13 of the Regulations, refers to the date written on the certificate.

ARTICLE 19. The announcements as stipulated in the Regulations and these Rules, after being issued by the OAPP, shall be published on China Pharmaceutical News.

ARTICLE 20. The OAPP shall maintain a Register of Administrative Protection of Pharmaceuticals in which any items relating to application and approval shall be recorded.

ARTICLE 21. The conditions under which a pharmaceutical granted with administrative protection may be revoked under Article 16 of the Regulations, refer to [conditions in which] the subject pharmaceutical is not in conformity with the provisions of Ar-

ticle 5 of the Regulations.

**ARTICLE 22.** Anyone who requests the OAPP to revoke administrative protection of a pharmaceutical in accordance with Article 16 of the Regulations shall submit a request and state the facts and reasons thereof, together with the relevant supporting documents, in duplicate.

**ARTICLE 23.** After the receipt of the request for revocation, the OAPP shall make an examination of it. Where the facts and reasons for revocation are not stated in the request or the reasons for revocation do not conform to Article 21 of these Rules, the request shall not be accepted by the OAPP.

The OAPP shall deliver a copy of the accepted request and copies of relevant documents to the owner of the exclusive right for administrative protection, and require him or it to submit his or its observations within prescribed time limit.

## CHAPTER V

### *The Fees*

**ARTICLE 24.** The fees, which shall be paid when an application for administrative protection is filed or when other procedures are gone through with the OAPP, are as follows:

- (1) application fee;
- (2) examination fee;
- (3) annual fee;
- (4) announcement fee;
- (5) certificate fee;
- (6) fee for a request for revocation;
- (7) fee for settlement of infringement disputes.

The amount of the fees listed above shall be prescribed by the SPAC separately.

**ARTICLE 25.** An applicant shall pay the application fee when he or it files application for administrative protection, [and shall] pay the examination fee and announcement fee within one month from the receipt date of the notification of acceptance. Where, without any justified reason, the payments are not made or are not made in full, the application shall be deemed to have been withdrawn.

**ARTICLE 26.** The owner of the exclusive right in a pharmaceutical shall pay the certificate fee, the announcement fee and the annual fee for the year within one month from the date on which the certificate for administrative protection is issued. During the effective term of administrative protection, the owner shall pay the annual fee for the year within the first two months of each year. Where, without any justified reason, the fees are not paid or not paid in full within the time limit, the administrative protection shall be deemed to be automatically given up by the owner.

ARTICLE 27. Where anyone requests the OAPP to revoke administrative protection of a pharmaceutical in accordance with Article 16 of the Regulations, he or it shall pay the fee for a request for revocation at the time when the request for revocation is submitted.

ARTICLE 28. Where the owner of the exclusive right in a pharmaceutical for administrative protection requests the OAPP to stop the infringing act in accordance with Article 19 of the Regulations, the owner shall pay the fee for the settlement of infringement disputes at the time when the request for such settlement is submitted.

ARTICLE 29. Various fees prescribed in Article 24 of these Rules shall be charged by the agency.

## CHAPTER VI

### *Supplementary Provisions*

ARTICLE 30. The SPAC shall be responsible for the interpretation of these Rules.

ARTICLE 31. These Rules shall enter into force on January 1, 1993.

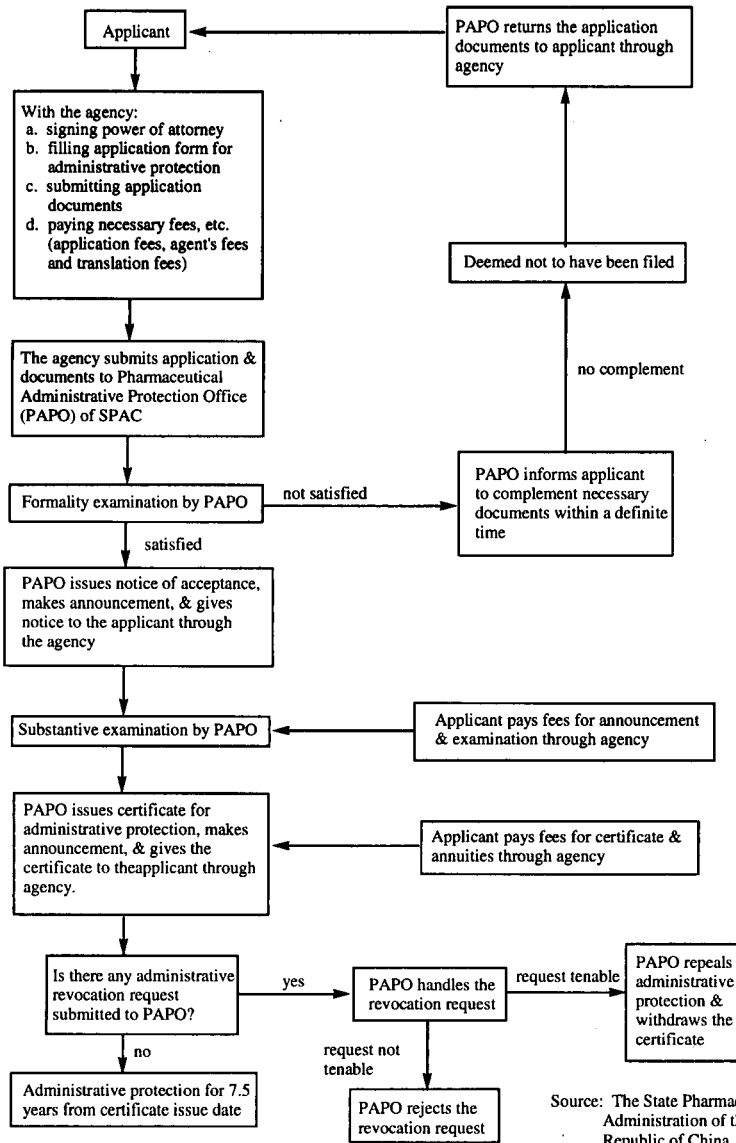
## Appendix C

SCHEDULE OF CHARGES FOR ADMINISTRATIVE  
PROTECTION OF PHARMACEUTICALS*Current as of July 23, 1997*

1. Huake Agent's Fee U.S. \$2,000
  2. Huake Inquiring Fee (per hour) U.S. \$100
  3. Application Filing Fee U.S. \$500
  4. Examination Fee U.S. \$5,000
  5. Certificate Fee U.S. \$100
  6. Announcement Fee U.S. \$100
  7. Annuity (Annual Renewal) Fees
  - 1st to 3rd year (per annum) U.S. \$2,000
  - 4th to 7.5th year (per annum) U.S. \$3,000
- Source: Huake Pharmaceutical Intellectual Property  
Consultative Center

Appendix D

Flow Diagram for Pharmaceutical Administrative Protection Proceedings



Source: The State Pharmaceutical Administration of the People's Republic of China