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Jiangsu Pengyao Drug Industry Co., Ltd. v. Hainan Hengxin Drug Industry Co., Ltd. et al.

Citation: The Guangxi Zhuang Autonomous Region Higher People's Court's Civil Judgment No.

Guiminsanzhongzi 11/2004

Date of judgment: September 28, 2004

Procedural history

The Hainan Hengxin Drug Industry Co., Ltd. (Hengxin) sued the Jiangsu Pengyao Drug Industry Co., Ltd. (Pengyao) and the Guilin City Xuifeng Zhenhui Drug Store (Zhenhui) in the Guilin City Intermediate People's Court for infringement of the exclusive right for the protection of its varieties of traditional Chinese medicine and for unfair competition. The first-instance court found the Pengyao's act of production constituted unfair competition. Pengyao appealed to the Guangxi Zhuang Autonomous Region Higher People's Court.

Issue

Whether a product to which the Certificate for the Protection of Variety of Traditional Chinese Medicine was granted by the State Drug Supervision Administration was specially protected as a variety of the traditional Chinese medicine?

Facts

Pengyao began to make, with approval, the "Kang Ai Ping Wan" (anti-cancer pill) from 1979, and granted the license to make the drug in 2002. Hengxin began to make Kang Ai Ping Wan also with approval from 1995, was granted the license to make the drug in 2002, and obtained the Certificate for the Protection of Varieties of Traditional Chinese Medicines issued by the State Drug Supervision Administration in Apple, 2002. Pengyao kept making and marketing said drug after Hengxin was granted the Certificate.

The first-instance Court held that Hengxin's being granted the Certificate for the Protection of Varieties of Traditional Chinese Medicines meant that it had secured the exclusive right for the protection of varieties of traditional Chinese medicines. The exclusive right belonged to the enterprise which had been granted said right. Pengyao disregarded the prohibitive provisions of the National laws and regulations; its act of making and marketing the drug had impact on the Hengxin's monopoly on the product in the market within the term of protection, and infringed the plaintiff's exclusive right for the protection of varieties of traditional Chinese medicines. Without being granted the Certificate, Pengyao's making and marketing the product by the same name as that of the plaintiff's product then under the protection were sufficient to create confusion on the part of consumers who did not naturally know about the law of the protection of varieties of traditional Chinese medicines, would mistake Pengyao's product for Hengxin's that was under the protection of varieties of traditional Chinese medicines. Pengyao had infringed Hengxin's right for the protection of varieties of traditional Chinese medicines.

Pengyao argued in its appeal that the present case fell outside the jurisdiction of the court accepting it; the issue of the eligibility for making and marketing "Kang Ai Ping Wan" was one concerning whether the State administration would cancel its approved market access based on the administrative license, rather than the civil relationships between unequal interested parties. The present case was not an IP case, nor was any of the IP-related rights involved, such as the copyright, patent right, trademark right, or the rights in a know-how. The protection of varieties of traditional Chinese medicines was devoid of the important legal character of the IP right. That is, the IP right was an absolute, exclusive right; while in the protection of varieties of traditional Chinese medicines, the existence of the right to make drugs of the same kind only required going through the necessary regulatory procedure.

Rule of Law

Article 2 of the Unfair Competition Law *A business operator shall, in its market transaction, follow the principles of voluntariness, equality, fairness, honesty and credibility, and observe the generally recognized business ethics.*

The "unfair competition" mentioned in this Law refers to a business operator's acts violating the

provisions of this Law, infringing the lawful rights and interests of another business operator, and disrupting the socio-economic order.

Article 17 of the Regulations on the Protection of Varieties of Traditional Chinese Medicines An approved varieties of traditional Chinese medicine, within its term of protection, shall be made by an enterprise granted the Certificate for the Protection of Varieties of Traditional Chinese Medicine.

Article 1 of the Ministry of Health's Notification on the Administration of Identical Varieties in the Work on the Enhanced Protection of the Varieties of Traditional Chinese Medicine (No. Weiyaoфа 23/1995) Under Rule 17 of the Regulations on the Protection of Varieties of Traditional Chinese Medicines. An approved variety of traditional Chinese medicine, within its term of protection, shall be made by an enterprise granted the Certificate for the Protection of Varieties of Traditional Chinese Medicines, and any other enterprise that is not holder of the Certificate shall not imitate and produce it.

Article 3 Enterprises involved with the same variety and not being granted the Certificate shall cease their production from the date on which the Ministry issued the Public Notification, and report to the Ministry as required within six months. The State Accreditation Board concerning the protection of the varieties of the traditional Chinese medicine, will organize the relevant entities to check the quality of the identical varieties. According to the check findings, the Ministry will then issue the Certificate for the Protection of the Varieties of Traditional Chinese Medicine to those that have met the regulatory drug provisions and the national drug standards upon consulting with the State competent agency for the administration of production and operation of the traditional Chinese medicine; the Ministry will cancel its approval of the production of the variety of drug by those enterprises that have failed to meet the regulatory drug provisions and the national drug standards.

Reasoning

The Regulations on the Protection of the Varieties of Traditional Chinese Medicine, formulated mainly for the purpose of curbing repeated production of poor quality traditional Chinese

medicine, have provided for a system for market access for the production of the Chinese medicine, but not for establishment of an IP system in the area. The Regulations did not grant Hengxin the exclusive civil right for protecting varieties of traditional Chinese medicine. Pengyao's production of said drug without being granted the Certificate did not constitute unfair competition.

The Regulations had only provided for the administrative and criminal protection, but not the civil protection, of the species and varieties of traditional Chinese medicines. The dispute arising between interested parties from their making and marketing the traditional Chinese medicine was not a civil one, and should be handled by the relevant State administrative agency.

Holding

Although the Certificate for the Protection of the Varieties of Traditional Chinese Medicine was granted by the State Drug Supervision Administration to the product made by Hengxin, Hengxin did not have the exclusive right for the protection of the varieties of traditional Chinese medicine in relation to that product.