

# BIOTECHNOLOGY PATENTING IN INDIA: WILL BIO-GENERIC LEAD A "SUNRISE INDUSTRY" TO BIO-INNOVATION?

Janice M. Mueller\*

## I. INTRODUCTION

Biotechnology patenting in India is still in its infancy in 2007. Three factors are primarily responsible. First, product patents on substances capable of use as medicine, drug, or food could not be obtained from the Indian Patent Office prior to January 1, 2005, when India completed implementation of TRIPS-required amendments to its Patents Act.<sup>1</sup> Second, even though process patents had always been available (albeit with short terms<sup>2</sup>) despite the pre-2005 ban on chemical product patents, it was not until 2002 that a court overturned the Indian Patent Office's policy of rejecting claims to processes that produced a live product.<sup>3</sup> Third, India's patent laws were amended in 2002 to explicitly include

---

\* Professor of Law, University of Pittsburgh School of Law; Visiting Professor, Seattle University School of Law (Spring 2008 semester). Email: mueller2@pitt.edu. University of Pittsburgh international law librarian Linda Tashbook and law students Matthew Lubniewski, Joseph Hsiao, and Andy Gabriel provided significant research assistance. Gregory York, a student at the University of Michigan School of Law, provided helpful comments.

<sup>1</sup> See Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 4 [hereinafter 2005 Patent (Amendment) Act] (repealing Section 5 of the law then in effect, Patents Act, 1970, Acts of Parliament, 1970, amended by Patents (Amendment) Act, 2002, Acts of Parliament, 2002), available at <http://www.patentoffice.nic.in/ipr/patent/patents.htm> (containing "principal" act – the Patents Act, 1970 – and all subsequent amendments). The prior law had prohibited the grant of patents on substances capable of use as food, medicine, or drug, see Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 5(1)(a), as well as the grant of patents on substances prepared or produced by chemical processes, "including alloys, optical glass, semi-conductors and inter-metallic compounds." *Id.* § 5(1)(b).

<sup>2</sup> See Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 53(1)(a) [hereinafter 1970 Patents Act]. The Act provides:

the term of every patent granted under this Act shall . . . in respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter.

The "date of sealing" in this provision was basically the date of grant, while the "date of the patent" was apparently the date on which the complete specification had been filed. See *id.* §§ 43, 45(1). In addition to the short term, chemical process patents were automatically deemed subject to the grant of "licenses of right," under which they could be practiced by any licensee for a four percent of bulk sales royalty beginning three years after grant. See PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY 38 (4th ed. 2004).

<sup>3</sup> See *Dimminaco A.G. v. Controller of Patents, Designs & Trade Marks*, (2002) I.P.L.R. July 255, 269 (Calcutta H.C.) (reversing Indian Patent Office's refusal to allow claim to "process of preparation of infectious Bursitis Vaccine," where end product of claimed process contained a live virus).