

that need to be followed. Further, compulsory license also hindered the procedure as this provision was meant to be used only to meet domestic demand of the country and not for export or import. However, this provision was ratified in the Doha ministerial meeting in November 2001, which is generally referred to as Paragraph 6 decision, for member countries with insufficient or no manufacturing capabilities³. This development, though laudable, has far less importance as the process is a burden for the member country with insufficient or no manufacturing capacity, as any member country needs to invest sufficient amount of money and time. It is evident, from the past, that no member country has ever used this flexibility so far. Certain countries threatened to issue compulsory license to negotiate prices of drugs for government procurement, but did not issue compulsory license as they felt the threat of trade sanctions from cer-

tain advanced countries. This provision of compulsory license is just to 'fool around' with socially and economically weaker countries. As majority of member countries are developing or underdeveloped, it is quite possible that they may not be able to use the flexibilities available to them. Thus, issue of compulsory licensing has far-reaching implications on certain developing and underdeveloped countries. Though WTO has tried to facilitate over a period of time to use the flexibility of compulsory license, lot more proactive steps need to be taken and member countries should be given more flexibilities for issuing compulsory licensing with least limitations, so as to protect public health and make required medicines available at an affordable price.

1. Article 31, Trade Related Aspects of Intellectual Property Rights (TRIPS agreement).

2. Compulsory licensing of pharmaceuticals and TRIPS. Accessed at http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm on 01-01-2006.
3. WT/MIN(01)/DEC/2, Declaration on the Trips agreement and public health. Adopted on 14 November 2001.

MANTHAN D. JANODIA¹
J. VENKATA RAO²
N. UDUPA^{1,*}

¹Department of Pharmacy Management, and
²Department of Pharmaceutical
Biotechnology,
Manipal College of Pharmaceutical
Sciences,
Manipal Academy of Higher Education,
Manipal 576 104, India
*e-mail: n.udupa@manipal.edu

Human tumour tissue bank: an essential requirement for Indian tumour biology research

Molecular, biochemical, proteomic, kinetic, statistical and bioinformatics studies on tumour or cancer-related diseases require direct human samples. All profiling techniques like DNA microarray, tissue microarray, two-dimensional gel electrophoresis and other modern techniques require different parts of the human tumour tissue (HTT)¹. The techniques demanded by these studies are mostly available in CSIR, DST, DBT and ICMR research institutes and not in surgical hospitals, central and state universities or district general hospitals. For advance research on tumour biology in India, there is a need for easy availability of HTT. For this, human tumour tissue bank (HTTB) is now an essential requirement. The problem of unavailability of HTT is usually faced by basic and applied research scientists. This is a big hindrance for scientists who work on basic tumour research in India. In the United States, there are government organizations to provide a national facility for greater access to HTT to scientists involved in cancer research. On the initiative of the National Cancer Institute, a cooperative human tissue network was established in USA² in 1987. This network is responsible for prospective procurement, preservation and distribution to institutional review board-approved investigators³. The

cancer therapeutic evaluation⁴ program includes several clinical trial cooperative organizations, which are also facilitated by the National Cancer Institute (www.nih.ohrp.gov).

Recently, an International Society of Biological and Environmental Repositories (ISBER, www.isber.org) has been established to assist in the development of standards in methodology, management and education. ISBER is a great informational resource for groups involved in procurement systems and repositories. Samples can be stored as snap-freeze, to keep them fresh or stabilize the tissues in fixative. At the annual meeting of the ISBER (2002), it was reported that whole cells maintained at -132°C or lower, exhibited the best long-term viability with minimal or no enzymatic degradation. India should also have a proper cooperative committee for accessibility of this stored specimen. This committee could recommend and recognize needful investigators. All stored samples and their related documents should be stored in a national facility, from where any recognized researcher can access these specimens and data.

Considerable efforts are now being made internationally towards developing standardized methods of tissue procure-

ment and processing. Biotechnology has made great strides to facilitate rapid unravelling of disease etiology. These have finally led to the development of better therapeutic targets. India should also take some effort on this front. This is a critical issue that needs effort through joint cooperation between government and private research centres and surgical hospitals.

1. Florell, S. R., Coffin, C. M., Holden, D. A., Gerweis, J. W., Summers, B. K., Jones, D. A. and Leachman, S. A., *Mod. Pathol.*, 2001, **14**, 116-128.
2. Clausen, K. P., Grizzle, W. E., Livolsi, V., Newton, W., Pretlow II, T. G. and Aamodt, R., *Cancer*, 1989, **63**, 1452-1455.
3. Livolsi, V. A., *Am. J. Clin. Pathol.*, 1996, **105**, 260-261.
4. Ansher, S. S. and Scharf, R., *Ann. N.Y. Acad. Sci.*, 2001, **949**, 333-340.

SANJEEV KUMAR MAURYA

Department of Surgical Oncology,
Institute of Medical Science,
Banaras Hindu University,
Varanasi 221 005, India
e-mail: sanjeevjnp@yahoo.com