IN THE NEWS

Current Issues in Intellectual Property Rights

News and controversy continue to be generated by the issues surrounding intellectual property. Pressure groups are active on both sides of the equation: seeking more protection for the rights of inventors and producers, and pushing for improved access to the benefits of innovations in such fields as pharmaceuticals, software, and biotechnology. This is evident in the sampling of news reports from the second half of 2002 given below.

DIVERSION OF DISCOUNTED AIDS DRUGS

A British pharmaceutical company produced a low-cost AIDS drug destined for poor and dying patients in five African countries. However, one-fifth of these products were obtained by profiteers at the marked-down price and shipped back to Europe for sale at market prices with huge profits. The company, GlaxoSmithKline, says it lost almost $16 million in sales last year because of such reselling. One of its drugs sells for $4 to $6 a pill in Europe, but for only 80 cents in sub-Saharan Africa.

A German businessman and a French drug trader were arrested in October for their roles in the diversion. Police and investigators in Belgium, France, Germany and the Netherlands, as well as in Europol, the European police agency, believe there is a wide network of traffic in gray-market AIDS drugs. Suggested ways to track and stop South-North diversions include use of different colors, labels or pill forms (capsules and tablets) in the two markets.

Pressured by AIDS activities and health authorities in developing countries, some drug companies — including Merck, Bristol-Myers Squibb, Roche, and GlaxoSmithKline — have discounted their AIDS drugs by as much as 90 per cent for developing world markets. Others resist such discounting on the grounds that two-price tiers open the door to fraud and undermine the profit margins that make it possible to reinvest in additional R&D for essential new drugs. (See also articles on "Balancing Health Needs" and "Pricing Medicines" in this issue.)

UN GLOBAL DISEASE FUND ENCOURAGES USE OF GENERIC DRUGS

Buying cheaper generic drugs rather than costly brand-name ones is now the policy of the UN disease fund created in 2001. The Global Fund for Fighting AIDS, Tuberculosis and Malaria has a target of $7 billion to 10 billion per year for its work, has so far been given pledges for $2.1 billion, and has received requests from developing countries for $8 billion worth of assistance.

The Fund's recent decision will encourage manufacturers of generic drugs in Brazil, India and other countries to sell more in developing countries, in place of medications from patent-holders in the North. It may also prompt more price reductions by Northern manufacturers, as has already happened with some drugs for treating HIV-AIDS. In addition, the Fund's money will go further now that it can buy less expensive generic drugs and expand treatment to additional patients. Perhaps the clearest example of unmet needs is that only 30,000 of the estimated 30 million people with the AIDS virus in Africa are getting anti-retroviral drugs that are regularly applied in Europe and the U.S.

The Fund's policy is that countries it assists are required to buy the lowest-price drugs, use only drugs with guaranteed quality, and follow international and national laws.

FASTER MARKETING OF GENERIC DRUGS IN THE US

The US government has taken steps to allow cheaper generic drugs to reach the market sooner and to end delaying tactics by pharmaceutical companies that try to extend their monopolies for similar patented drugs. The US Food and Drug Administration estimated that its new rules would save consumers $35 billion over 10 years, out of $4.7 trillion in expenditures for prescription drugs. This will be of most help to older Americans who tend to have fixed or lower incomes and need more medications than younger people — analogous to the less-advantaged populations in developing countries who can benefit from internationally marketed generic drugs.

A 1984 U.S. law gave brand-name drug manufacturers patent protection and research incentives while also encouraging generic companies to sell low-cost copies of those medicines as soon as the patents expired. Under the new rules, brand-name drug makers would no longer be able to get long extensions of their 20-year patent monopolies by entering multiple lawsuits, obtaining patents on secondary elements like packaging, and raising other obstacles. A patent-holding company would be limited to only one 30-month stay against a generic competitor while a court resolves a claim of patent infringement.

MORE FLEXIBLE INTERNATIONAL RULES FOR INTELLECTUAL PROTECTION

A recent report has recommended a more flexible timetable for developing countries to adopt the rules of the Trade-related Intellectual Property Rights (TRIPS) agreement more at their own pace. Keeping to the present schedule, the TRIPS agreement in full effect would greatly increase the annual patent and royalty income of developed countries, but increase the costs to be paid by many developing countries. For example, according to World Bank estimates, annual gains would be $19 billion for American companies, $6.8 billion for Germany, and $5.7 billion for Japan, while net payments would go up by $5.1 billion a year in China, $2.6 billion in Mexico, and $900 million in India.

Issued by the Commission on Intellectual Property Rights (CIPR) sponsored by the United Kingdom, the report suggests other changes in TRIPS rules, such as allowing developing countries to:

- make greater use of compulsory licensing of drugs;
- copy software by making educated assumptions about the underlying codes, a process called "reverse engineering";
- "crack" software used to protect copyrighted digital media when a country determines that the protective technology limits the fair use of digital materials.

Part of the rationale for these recommendations was provided by Professor John H. Barton from Stanford University Law School, who led CIPR: "If we cut off imitation strategies for developing countries, we are drastically narrowing the options they have to reach an economic takeoff," he said (*New York Times*, October 14, 2002).

The situation of developing countries is similar to that of the United States in the 19th century, when American law offered no copyright protection to authors from other countries. Books from England, for example, were widely copied in America and sold at cut rates in the U.S. Finally in 1891, when a U.S. book industry had grown up and wanted protection abroad, the U.S. gave copyright protection for foreign authors in the U.S. when American authors received similar treatment overseas. Likewise in the 20th century, the economies of Japan, Taiwan and South Korea took off under weak systems of intellectual property protection, achieving easy and inexpensive technology transfer, until local industry developed and needed reciprocal international protection. According to the CIPR report, the opportunities for a jump-start in developing countries using imitative tactics is endangered by the scope, speed and strength of the global TRIPS agreement.