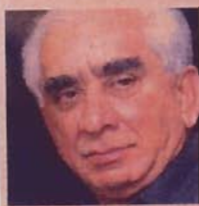


SATURDAY / SUNDAY 15/16 FEBRUARY 2003



The annual ritual

The Budget isn't an exciting affair any more

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Patents & health

Countries should invest more in new drug formulations

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Ahmedabad, Bangalore, Chennai, Hyderabad, Kolkata, Mumbai and New Delhi

Opinion

Patents and public health

Developing countries should increasingly invest in research to discover new drug formulations, says Sunil Chacko

A purely legal interpretation of the 'compulsory licensing' clause or Article 31 of the World Trade Organisation's TRIPS Agreement may lead to the belief that any government can authorise the royalty-free copying of the intellectual property held by any pharmaceutical company merely by declaring any disease as a 'national emergency.' That contention, at odds with how international finance and economics works in reality, has led to the slippage of negotiating milestones agreed to at the Doha WTO Ministerial Meeting, highlighting the fragility of the multilateral trading system. It is true that Article 31 provides for the legal possibility for any government, facing a public health crisis, to override patent rights and grant non-patent-holder companies the right to manufacture any medicine. However, the failure to define what constitutes an emergency has complicated the delicate balance between the rights of patent holders and patients. National emergencies in public health are often epidemics, which are defined as cases of a specific disease or disorder clearly in excess of what one would normally expect in a particular geographic area. By definition, the handful of Anthrax deaths that occurred in 2002 comprises an epidemic and the absolute horror that those few cases of Anthrax created was palpable everywhere, thereby also constituting a national emergency in more than public health terms.

Under international law, Article 31 of the inter-governmental TRIPS agreement provides the US government with the right to undertake compulsory licensing of the antibiotic Ciprofloxacin that destroys Anthrax. Virtually every disease, condition or disorder can be defined as an epidemic or emergency, especially in view of the abysmal health statistics in many countries. This is the crux of the bitter divide.

While R&D pharmaceutical companies insist on the protection of patents and strict limits to the number of diseases that can be defined as epidemics, most countries reject those restrictions. The acrimonious debate highlights the void between a pragmatic, multi-disciplinary approach to the problem and one that purely relies on a narrow reading of Article 31. Top pharmaceutical companies fear the loss of the market of 5 billion people who live outside established market economies.

Even the wealthiest countries count on an annual inflow of foreign direct investment to help counterbalance trade and budget deficits within macroeconomic accounts. The US and European countries secured over \$500 billion of foreign direct investment (FDI) in the past year despite the worldwide recession. These resources flow into countries on the basis of sound legal protections and respect for private and intellectual property rights, principles long championed by every US administration. Damaging those rights and protections is tantamount to a

large sign that states 'Foreign Capital Unwelcome Here.' Indeed, investors who have to commit their resources for decades in one country watch out for evidence of even subtle signs of disrespect for the rights of investors. If there is such perception, capital flees and takes a lifetime to reappear. In many developing countries where nationalisation was a pastime, FDI has consistently stayed away. National authorities of countries that are pursuing active economic reforms take no chances with FDI.

But there are important public health reasons underlying the likely continuing disagreements on what constitutes an 'emergency'. Epidemiological and demographic transitions are occurring globally, populations are aging and increasingly, cancer, cardiovascular and other chronic diseases are rampant in countries like China, India and Brazil. These too cause much suffering and death and will take hold in

all developing countries in the coming decades. This is why negotiators from underdeveloped nations win at the suggestion that Article 31 be restricted to AIDS, TB and malaria.

The answer to this quandary is for countries to invest in research and development targeted at developing new medicines, vaccines and diagnostics. While some countries have advanced science and technology that enables them to work on fundamental research, others can participate in clinical studies, and still others in bioinformatics data analysis to help define new molecular targets against deadly diseases. A scan of the products under development in several thousand pharmaceutical and biotechnology companies in the US, Canada, Europe, Japan and many advanced developing countries such as India, China, Brazil, Thailand and South Africa indicate that there are so many promising products that can help patients.

Many individually cannot replace blockbuster drugs that will continue to serve wealthier markets. But hundreds, especially in combinations, could benefit people everywhere but will require much work to bring them through scientific safety, efficacy and effectiveness studies under conditions of high attrition probability and on to patients. It is up to agencies such as the World Health Organisation, the United Nations Development Programme, the World Bank and the Bill and Melinda Gates Foundation to take up this important challenge to help countries and companies worldwide overcome capacity constraints in research, development and quality manufacturing. Expropriating someone else's intellectual property is not the answer.

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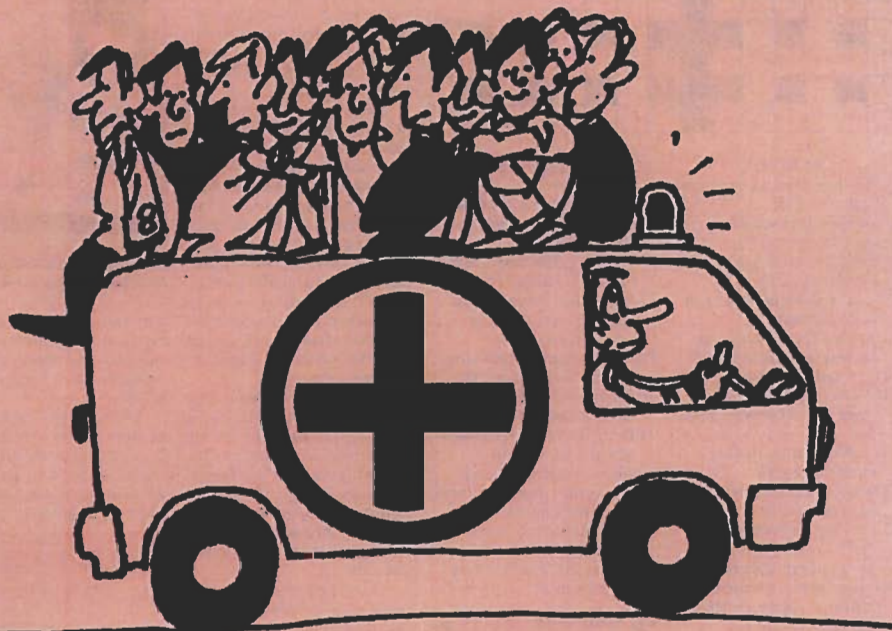


Illustration by R PRASAD