Plagiarized report on patent laws shames Indian scientists

In a major embarrassment to Indian science, one of India's best known scientists Raghunath Mashelkar, who recently retired as head of the prestigious Council of Scientific and Industrial Research (CSIR), has acknowledged that parts of a government committee report authored by him were plagiarized.

The report, which was intended to settle a dispute on India's patent law, has instead itself become a matter of contention. The committee's high profile has dragged the incident into the international spotlight. Though the Indian government gave Mashelkar three months to resubmit the report, he resigned in March as head of the committee.

"The incident will dent India's image abroad and shake the confidence of Indian scientists in the government protecting their intellectual property interests," says Ashok Parthasarathy, former science adviser to the Indian government.

In April 2005, India changed its laws to conform to intellectual property rules set by the World Trade Organization (WTO). But the laws allow only drugs that are seen as entirely new chemical entities to be patented, severely limiting drug makers' ability to profit from drugs that are viewed as being only incrementally different.

Not surprisingly, multinational companies have protested against the law, saying it is a violation of the WTO rules.

To resolve the matter, the Indian government in April 2005 appointed a committee headed by Mashelkar, who is deputy president of the UK-based Institution of Chemical Engineers and president of the Indian National Science Academy, to examine the issues and make recommendations on the law.

After nearly two years of research, the committee on 29 December submitted a report that was largely favorable to the multinational companies, concluding that India should allow patents on drugs with incremental improvements.

The recommendation proved handy to Swiss company Novartis, which last May filed a lawsuit against the Indian government for rejecting a patent application on its cancer drug Gleevec. In February Novartis cited the Mashelkar committee report to support its case.

The lawsuit has gained international attention, with the humanitarian organization Médecins sans Frontières (MSF) launching a global petition urging the company to drop the case. A win for Novartis, says MSF, could jeopardize the supply of cheap HIV medicines. India supplies more than 80% of the AIDS drugs used by MSF worldwide.

Several public interest groups, including the National Working Group on Patent Laws (NWGPL), a group of legal and scientific experts that helped draft the patent laws, immediately slammed the report. "The report contained a number of untenable propositions and is oriented to favour foreign drug companies," says Parthasarathy, who is a member of NWGPL.

On 12 February, two Indian newspapers carried reports that parts of the Mashelkar report had been plagiarized from a study by the UK-based think tank Intellectual Property Institute, funded by Interpat, an association of 29 drug companies including Novartis.

The following week, Mashelkar withdrew the report, saying it contained "technical inaccuracies" that had escaped the notice of the committee members. "It is an error of oversight, but I stand by its contents," Mashelkar told *Nature Medicine*.

But some scientists say the committee was biased from the start and did not consult objective experts.

"There is no record of discussions with technical experts on the subjects," notes Pushpa Bhargava, founder director of the Centre for Cellular and Molecular Biology in Hyderabad.

"One and a half years is a long enough time for a detailed review of a subject that is not only technically complex but also has enormous public health implications," adds Gautam Desiraju, professor of chemistry at the University of Hyderabad.

NWGPL's convenor Bal Krishan Keayla says the committee did seek input from the working group, but does not appear to have taken them into account. "We made a series of recommendations but no mention is made of them in the report," Keayla says.

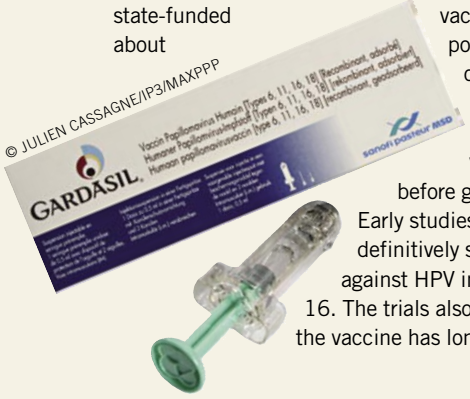
In the meantime, the plagiarism charge has proven useful for activists trying to discredit the report on grounds of bias. "The public can understand plagiarism better than intricate intellectual property issues," says Mira Shiva, board member of Health Action International-Asia Pacific, a non-profit global network working toward equitable access to medicines.

T.V. Padma, New Delhi

Controversy over cervical cancer vaccine spurs safety surveillance

When Gardasil, the first vaccine against human papilloma virus (HPV), was approved in June 2006 by the US Food and Drug Administration, it was widely hailed as a godsend for women.

Clinical trials involving more than 20,000 women showed the vaccine to be safe and effective. But the vaccine's rapid adoption—Texas has already made immunization mandatory for preteen girls and 34 other states are considering either mandates or state-funded vaccination—has stirred debate about potential risks that may have been overlooked in the vaccine's trials.



© JULIEN CASSAGNE/IP3/MAXPPP

Because the virus is spread through sexual contact, the vaccine must be administered before girls become sexually active. Early studies did not run long enough to definitively show that the vaccine protects against HPV infection in girls younger than 16. The trials also didn't determine whether the vaccine has long-term side effects, is active beyond five years or is compromised when given along with other adolescent vaccines for meningitis, diphtheria, tetanus and pertussis.

Learning from incidents where the public shunned vaccines because of unfounded fears of side effects—such as autism or multiple sclerosis—scientists are conducting large-scale studies to address questions about Gardasil.

"It has become a consideration in introducing vaccines: you must have surveillance," says Paul-Henri Lambert, chair of the WHO's Global Advisory Committee on Vaccine Safety.

Some strains of HPV are thought to cause cervical cancer, which kills more than 250,000 women every year, mostly in developing countries. Gardasil protects against the two strains that are linked to more than 70% of cervical cancer cases. Another vaccine, GlaxoSmithKline's Cervarix, targets the same strains and is now in phase 3 trials. It is likely to be submitted to the FDA this year.

Early reports from the US Vaccine Adverse Events Reporting System suggest that, at least in the short-term, Gardasil is safe. "The number, type and severity of the events reported at this point are basically consistent with the safety data collected in the pre-licensing period,"