

RED FLAG

Report faults US patent system on biotechnology, calls for change

Using Myriad Genetics as case study, report says system needs revamping to increase patient access to drugs

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The intellectual property, or IP, system in the US is “broken” and needs immediate transformation to ensure that biotechnological advances and ensuing treatments reach the patients across the world, says a new report released in Washington on Tuesday.

Prepared by the Montreal-based International Expert Group on Biotechnology, the report is based on a series of case studies that analyze how biotech companies are protecting and enforcing their patent rights globally, particularly in genetic diagnostic tests.

“Patent holders are not doing a good job of sharing information and biotechnological tools to foster innovation and access to vital genetic data,” the authors note.

Titled *Toward a new era of Intellectual Property: From confrontation to negotiation*, the report documents the mistakes made by Utah-based Myriad Genetics Inc. in protecting its IP on breast cancer genes in the US and elsewhere. And contrary to what the industry has argued, authors say, “Myriad’s hardball tactics are the norm in the biotech and pharmaceutical industry.”

Some of the tactics that damaged Myriad’s reputation

TRANSITIONING TO A NEW IP ERA

TRUST: ‘Old IP’ continues to undermine trust, which is essential to meeting the challenge of remaking this system so that research networks result in the creation, sharing, improvement and combination of knowledge. For now, governments do not have the capacity to step back and facilitate relationship-building. Outsiders must fill this role.

NEW MODELS: To stress sharing over hoarding, and partnership over barriers. Examples: a pool of patents set up by UNITAID to deliver needed HIV/AIDS medications to the world’s poor.

DATA AND METRICS: Right now, we measure the wrong things about IP, particularly at public institutions and universities. Unless we figure out what we want from innovation and how to measure it, we will not break out of the vicious cycle of Old IP.

CROSS-CUTTING THINKING: More attention needs to be paid to understanding how IP contributes to the overall functioning of the innovation system rather than deal with it in isolation.

TRANSPARENCY IN PATENTS: Private sector should be open about what patents they hold; patent offices should collect patent-related information in a standard form to make it available to the public for free. Data should include information that will assist in assessing patent landscapes in targeted areas of technology, such as essential medicines.

Source: International Expert Group, Canada

PARAS JAIN/MINT

and harmed its business interests—where it faced resistance and revocation of patents from some countries—are repeated by other companies, says co-author Robert Cook-Deegan of Duke University. “Such actions are affecting genetic testing for several diseases, including Alzheimer’s disease and Long QT syndrome, a condition that can make carriers extremely vulnerable to sudden cardiac death.”

Breast cancer tests, based on mutations in BRCA1 and BRCA2 genes (patented by Myriad), have been offered in India since 2005 by Reliance Life Sciences which, it says, is the only organization testing these mutations for familial and/or early onset breast cancer in India.

“Myriad and Cancer Research UK (another patent holder) have not filed patents in India and therefore there is a freedom to operate in India,” says K.V. Subramaniam, president and chief executive of Reliance Life. He says the high price of the tests—\$3,125, or Rs1.49 lakh—might have acted as a deterrent for its launch in India.

But the situation could get tricky now. India, since 2005, has to comply with a stricter patent regime and is becoming an attractive market as more genomics-based diagnostics and drugs roll out from the companies.

Beyond this is the general problem that the biopharmaceutical industry is producing fewer and fewer new drugs

and, of these, more and more are “me too” drugs, says Richard Gold, chairman of the experts group from McGill University.

“This is a worry not only to the populations that rely on new medicines but to the companies themselves as they will have fewer products on which to support their enterprises,” he wrote to *Mint* in an email.

Gold believes there are examples in other related areas, such as indigenous knowledge where, for example, his team found so many competing rights in Brazil that it was impossible to conduct research.

The report derives from more than 10 years of data from 17 countries, including India. It concludes that if patent holders don’t change their behaviour and government agencies don’t act, “pressure will grow on legislators to intervene”.

The study is timely in that it urges us to rethink an old regime that may not necessarily suit the needs of a rapidly “cumulative innovation industry” such as biotech, says the newly added member to the expert group from India, Shamnad Basheer, a visiting scholar at the Max Planck Institute of Intellectual Property in Munich.

Apart from the Council of Scientific and Industrial Research’s move to adopt open source strategies towards biopharmaceutical research and development, Basheer thinks alternative paradigms such as prizes and advance purchase commitments are emerging.

“We must be open to the idea of trying out some of these new incentives that can spur innovation”, Basheer says.

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