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Genetic diagnostics companies speed ahead

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The playing field for research and development for genetic diagnostics has been leveled. The landmark decision by the US Supreme Court on June 13, 2013, stating that human genes cannot be patented satisfactorily concluded the lawsuit against Myriad Genetics, a molecular diagnostics company that was trying to protect its US patents on the BRCA1 and BRCA2 genes - prognosticator of breast cancer. It is the first time that the US Supreme Court invalidated a human gene patent.

This ruling will most likely result in invalidating at least another 3,500 patents involving human genes, according to a study. So, what is the incentive to develop gene diagnostics when the intellectual property cannot be protected?

The fact is that the ruling still protects the intellectual property related to innovation in genetic diagnostics. However, the era where gene sequencing itself was a great leap is over. Mere discovery does not merit patent. Questions about what the innovator does with the discovery, its utility and the degree of innovation reign. This has opened doors to all companies, institutes and individuals with relevant skill sets. As we have seen across economies, enabling healthy competition makes a great difference. The result invariably always is better products that reach the market quicker and at competitive price points. In this case too, it is a win-win for both the patients and the about $30 billion global molecular diagnostics industry, which is expected to treble in size before the end of this decade.

Now, it is upto the molecular diagnostics companies in the industry to adopt business models that will bring value to their respective markets. Most of the large companies in the US and Europe have already seized the opportunity and their products, including now off-patent breast cancer diagnostics, are slated to hit the market by end of 2013. These companies have put in place business models that rely on additional value in interpreting the results and providing genetic counseling. While most of the action in this field is happening in US, the companies in Asia are not far behind.

Malaysian company Sengenics is a case in point. The company that offers at least 400 molecular diagnostics products based on its cutting-edge genomics and proteomics technologies has recently entered into a strategic marketing agreement with Gribbles Pathology (part of Healthscope, a healthcare operator from Australia) for the Malaysian market and intends to generate in excess of $25 million in revenue in its first year of operation.

In India, Chennai-based XCode Life Sciences, founded by Dr Saleem Mohammad, assesses four lifestyle disorders: diabetes, obesity, cardiovascular diseases and stroke. Each test is being offered at $150 and uses non-invasive saliva sample for diagnosis. XCode, in March this year, had bagged the BioSpectrum Emerging Company of the Year Award 2013 for its products and business model.

Another Indian company Hyderabad-based mapmygenome offers a composite report called Genomepatri that interprets genetic variations and its impact on a person in terms of susceptibility to major diseases and also connects its customers to genetic counselors and other relevant experts. Its founder Ms Anuradha Acharya is one of the first few entrepreneurs in India to offer such a product.

These examples from Asia showcase that the rush to leverage on the genetic diagnostics opportunity has just begun in Asia.