Evaluate Vantage

August 07, 2013

Ambry Genetics could end up benefiting from Myriad lawsuit

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It takes more to slow down Myriad Genetics than a mere ruling against it by a two-bit organisation like the US Supreme Court. The former monopolist of the US genetic breast cancer diagnostics market has sued rivals Ambry Genetics and Gene by Gene after they launched BRCA gene tests with the justification that the highest court in the land said they could.

Now Ambry has hit back with a suit of its own, and seems likely to prevail – eventually. Potentially more significant in the long run, however, is Ambry's decision to release data on an aspect of its test's predictive value, in response to allegations in the Myriad suit. The data suggest that Ambry's product is better than thought; Myriad's litigation could yet backfire nastily.

Variants of unknown significance

Myriad had maintained its sole command of the BRCA gene testing area by claiming to have patented the very genes the test detects. In June, the justices overturned the notion that human genes could be patented, and Ambry, Gene by Gene and others rushed their tests out (*Myriad's BRCA monopoly crumbles after Supreme Court denies gene patents, June 14, 2013*).

Myriad has now changed tack, insisting that Ambry's test infringes patents covering synthetic DNA and methods of use related to the BRCA1 and BRCA2 genes. Myriad is also seeking an injunction to prevent Ambry and Gene by Gene selling their tests. Ambry's countersuit was filed under antitrust laws, and alleges that Myriad's suit was designed to "intimidate and chill competition".

Ambry has also claimed that Myriad sent letters to doctors containing false information about the rate at which it detects variants of unknown significance (VUS). Most of the time BRCA tests find that a patient's gene is normal or mutated in a way that raises their chance of developing cancer. Sometimes, though, the test detects a mutation that may or may not be associated with increased cancer risk – its implications for the patient's health are unknown.

A diagnostic's VUS rate can be improved over time as the test's developer follows the patients carrying mutations whose significance is not yet understood. The mutations can then be linked with increased or unchanged risk, boosting the test's predictive value.

Much better

To hear Ambry tell it, Myriad has been misinforming doctors by saying that Ambry's BRCA1/2 test has a VUS rate of up to 30%. This has prompted Ambry to state formally for the first time that the rate is actually 5%, which Dan Leonard, an analyst at Leerink Swann, says is "much better than anticipated, if true". He said the VUS rate of non-Myriad BRCA tests was previously unknown, but had been thought to be higher – between 10% and 30%.

Mr Leonard stated that Myriad's BRACAnalysis test has a VUS rate of less than 3%.

Ambry has already achieved some BRCA share so far, he said, thereby disproving the thesis that doctors would not order a BRCA test with a higher VUS rate than Myriad's BRACAnalysis. Of course, if a test with a high VUS rate were never used, its developer would not be able to obtain the data on VUS carriers necessary to improve the test, and the VUS rate would remain high.

With a lower VUS rate than previously thought, this fate does not seem likely to befall Ambry's diagnostic. If Ambry can shake Myriad's patent claims, as many watchers appear to expect, Myriad's market share could erode even faster than it would have if the company had never called the lawyers in the first place.

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