

## Sequenom becomes second casualty of Myriad ruling



[Elizabeth Cairns](#)

It is beginning to look as if relying on patents covering naturally-occurring molecules might not be a good strategy for diagnostics companies. Following the rug-pull the US Supreme Court delivered to Myriad Genetics by disallowing its patents covering breast cancer genes, a patent covering foetal cell-free DNA in the bloodstream of pregnant women underpinning Sequenom's Down's syndrome test has also been struck down.

The resulting share price fall of 22% last week seems a little harsh bearing in mind that the case, filed by competitor Ariosa Diagnostics, is not yet over – it will now go to appeal – and anyway, unlike Myriad, which had successfully kept competitors away, other Down's tests are already on sale. But losing IP is never a good thing, and Sequenom shareholders were doubtless hoping for a cash award which the struggling company could definitely use.

### Natural phenomenon

Sequenom launched its MaterniT21 diagnostic, which tests for foetal chromosomal abnormalities including trisomies 21, 22, 16, 18 and 13 as well as other genetic defects, in October 2011, gaining first-mover advantage. Ariosa filed its suit two months later, citing "repeated public threats by Sequenom" regarding enforcement of patent US 6,258,540.

Ariosa was after a judgment that its Harmony test did not infringe Sequenom's patent. In January 2012, Sequenom counterclaimed for patent infringement and sought a preliminary injunction. The injunction, which would have forced Ariosa's test off the shelves, was denied in July 2012.

The '540 patent covers the detection of nucleic acid of foetal origin in a serum or plasma sample from a pregnant woman. The US District Court in Northern California invalidated it, determining that a natural phenomenon is not patent-eligible and specifically citing the Myriad case as a precedent ([Myriad's BRCA monopoly crumbles after Supreme Court denies gene patents, June 14, 2013](#)).

Sequenom has vowed to appeal, insisting that there is a distinction between a novel use of a natural phenomenon and the phenomenon itself. It is also embroiled in litigation with Verinata – since bought by Illumina – and Natera, both of which have similar tests. These are also based on the '540 patent so it would seem likely that these cases will also go against Sequenom.

### Sell up?

If Sequenom's appeal is unsuccessful, it will lose all hope of a cash judgment from Ariosa to bolster its cash on hand, and will also be open to untrammelled competition. This comes at a bad time, as the company laid off 75 workers, about 13% of its workforce, in August, which it attributed to delayed payments from insurers, Medicare and Medicaid following code changes.

With its market cap having sunk to just \$220m, down 60% this year, Sequenom might be a potential takeover target. Kevin DeGeeter, an analyst at Ladenburg Thalmann, believes that MaterniT21's high service levels and first mover status provide a residual competitive advantage. Sequenom was already looking at selling off its genetic analysis arm; perhaps it will now consider selling up entirely.

Meanwhile, other diagnostics companies with patents related to unaltered DNA and other natural phenomena might want to get the attorneys on the phone. Their patent coverage might not be quite as secure as they thought.

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