

## Patent Law – The Case of Sequenom

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1. Sequenom is a biotech company that bought the license of U.S. Patent based on a method that uses cell-free fetal DNA (cffDNA) or tell-tale DNA that is circulating in maternal plasma as a prenatal test. Through this achievement it was able to diagnose fetal abnormalities without proceed invasive methods such as amniocentesis that could carry several risks.
2. Other companies such as Ariosa Diagnostics, Inc. developed similar testing methods. The controversy between them was led to the district court in 2013 which defined the patent of Sequenom as invalid. At a next level, the Federal Circuit decided to invalidate Sequenom's patent stepping on previous decisions of Supreme Court for cases like Mayo vs Prometheus. According to this, the patent in discuss concerns the discovery of a natural phenomenon and includes procedures that are already known (not innovative). Furthermore, the Supreme Court denied hearing the case and the petition for a writ of certiorari.
3. There were not arguments against this application as such from other groups. But it was noted that it is very important for the existence and the evolution of a biotech company to develop gene patents or gene-based patents. In that way all the necessary capital could be found and invested in that company.
4. After the Supreme Court's denial, there were several judges that expressed their objections based mainly to the case of Mayo concerning the risk of placing barriers to biotechnology patents and innovative applications. The refusal of recognizing this method as innovative and thus as patentable, worried also the biotechnology law world about the broadness up to which patents could be invalidated. It was asked that Supreme Court's decisions on biotechnology patents should be able to clarify and better define the frame where biotechnology patents are more possible to be developed and eligible rather than cause controversies.
5. As a Committee member of a Patent Office, I would suggest not to grant the patent since the method patented is based on a discovery of a natural phenomenon and not an invention. The method also uses procedures and activities that are already well known such as amplification and DNA amplification. However, I would take into consideration that it could be widely industrial applicable and that the application to the maternal blood was novel.