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Comments Submitted by Anonymous #5

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Please consider the following in the context of my comments below:

https://www.uspto.gov/web/offices/pac/mpep/s2106.html
2106 Patent Subject Matter Eligibility [R-10.2019]
I. TWO CRITERIA FOR SUBJECT MATTER ELIGIBILITY
First, the claimed invention must be to one of the four statutory categories. 35 U.S.C. 101 defines the four categories of invention that Congress deemed to be the appropriate subject matter of a patent:
processes,
machines,
manufactures and
compositions of matter.
The latter three categories define "things" or "products" while the first category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term ‘process’ means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."). See MPEP § 2106.03 for detailed information on the four categories.

Second, the claimed invention also must qualify as patent-eligible subject matter, i.e., the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception. The judicial exceptions (also called "judicially recognized exceptions" or simply "exceptions") are subject matter that the courts have found to be outside of, or exceptions to, the four statutory categories of invention, and are limited to abstract ideas, laws of nature and natural phenomena (including products of nature). Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216, 110 USPQ2d 1976, 1980 (2014) (citing Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589, 106 USPQ2d 1972, 1979 (2013). See MPEP § 2106.04 for detailed information on the judicial exceptions.

Biotechnology companies and their investors need considerable amounts of capital to fund and accomplish the research, development, proof of concept, proof of safety, and proof of efficacy activities necessary to bring a high-quality diagnostic from invention to distribution. Small and medium sized companies in particular need the ability to patent their inventions so that their intelligent hard work is not simply poached by larger biotechnology companies who already dominate the market. Small and medium sized companies create and provide more jobs than large and very large corporations in the United States (https://www.nysscpa.org/news/publications/the-trusted-professional/article/more-americans-work-at-big-firms-than-small-ones-040717). For example, 63.8% of people were found to work for companies with 1-2,499 employees, while just 36.2% of jobs were offered by the large and very large companies with >2,500 employees. This suggests that medium-sized and small companies have historically created more jobs than large and very large companies. This further suggests that the USPTO needs to carefully scrutinize and consider the impact of their policies upon medium-sized and small companies and the return enjoyed by investors that help them start and grow.

Now, I understand you cannot pick and choose patent recipients based on their company size or other unfair criteria. Yet I believe it is important to scrutinize the trends of USPTO policy in the context of the intent of the Patent Act and effects on wealth and income inequality in the United States. Small-scale, independent, small company, and medium-sized company inventors need a fair opportunity to recover the costs of researching and developing their inventions. Specifically in the context of device diagnostics, the Association for Molecular Pathology versus Myriad Genetics was understandable in the context of naturally-sourced BRCA gene sequence diagnostics. To say that Myriad's cDNAs were patentable but the original gene sequence discovered in patients seems rational, however the cDNA's made from complementary bases contains the same information as the BRCA original gene. Large and very large companies have the ability to bundle such diagnostics with other products, funding such bundles with either corporate profits or the issuance of new stock shares. Small and Medium sized companies have a much more difficult time funding such large-scale bundle-development projects. The net result is that some human subpopulations with relatively rare nucleotide polymorphisms in their genome are less likely to access diagnostic help, because the companies that could help them cannot achieve patent protection for the diagnostic products and related software which USPTO has been finding to have originated from natural processes. Inventions based on new, innovative combinations of processes should be patentable.

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