

We are currently investigating whether, and how, the Supreme Court’s March 2012 decision in *Mayo v. Prometheus* affected patent applications and grants in the area of medical diagnostics.

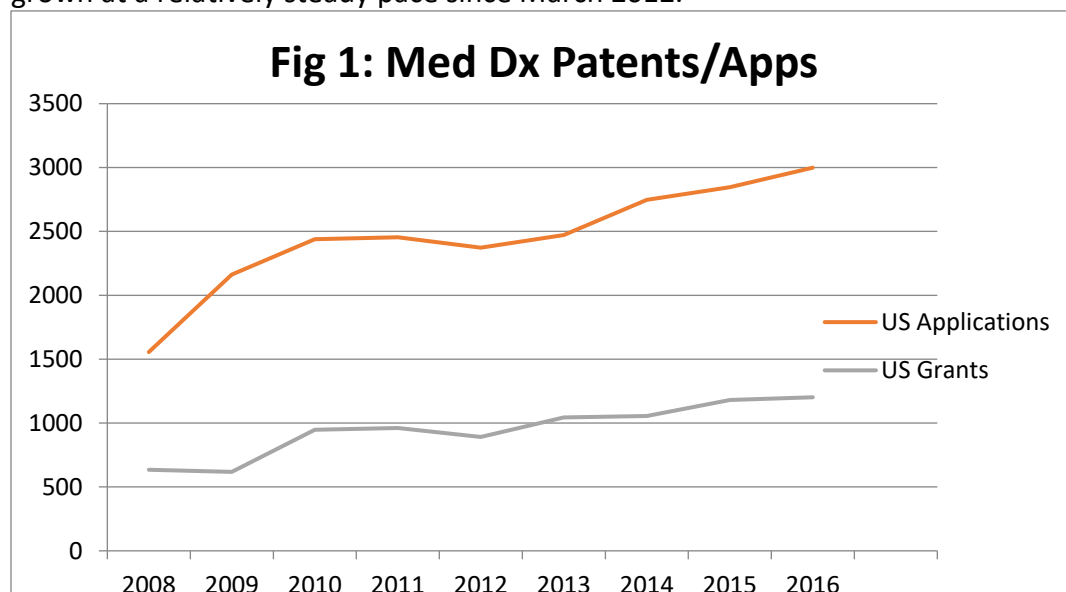
We define a medical diagnostic as a technique or instrument used to establish or confirm a medically relevant condition. Thus, diagnostics can include both simple tests based on one or a few biomarkers or complex tests that produce outputs based on computational analysis of many different biomarkers. Based on this definition, we identified a set of highly relevant CPC classifications. These are listed in Appendix A.

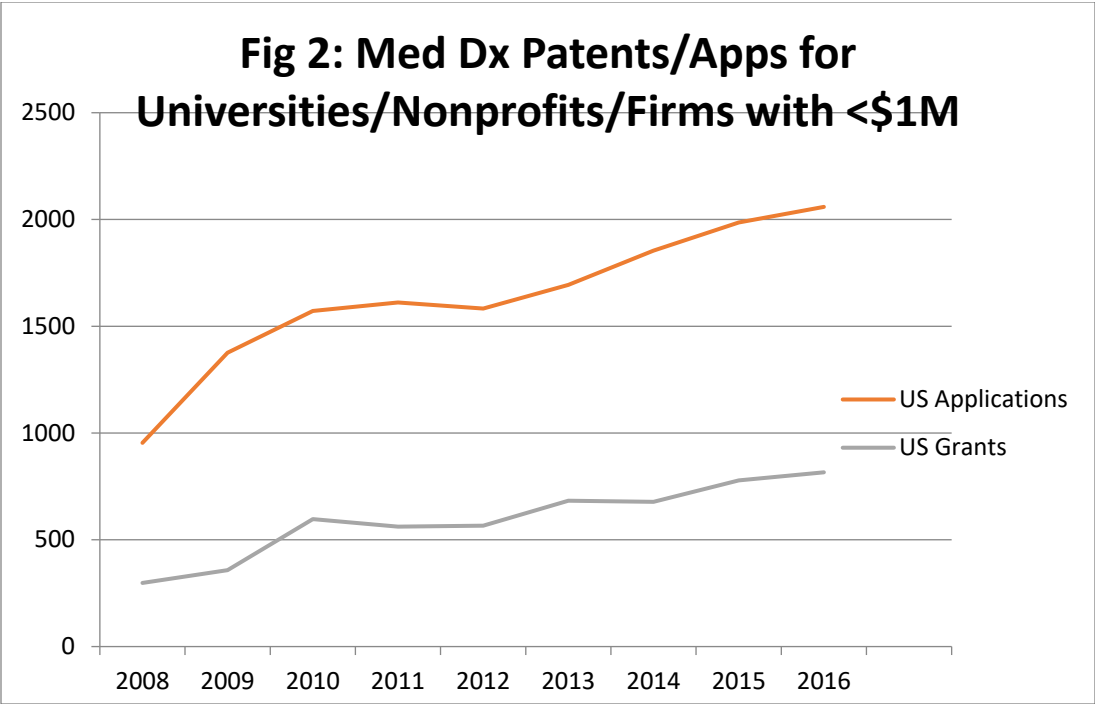
In order to minimize false positives, we were parsimonious in our CPC selection. Additionally, we selected patents based on first CPC classification only. Our CPC selection may, however, be underinclusive.

We implemented our CPC search using the Innography patent database tool. Because this platform is proprietary, we cannot disclose our underlying data. However, access to this platform is available for a fee, and our search can therefore be replicated.

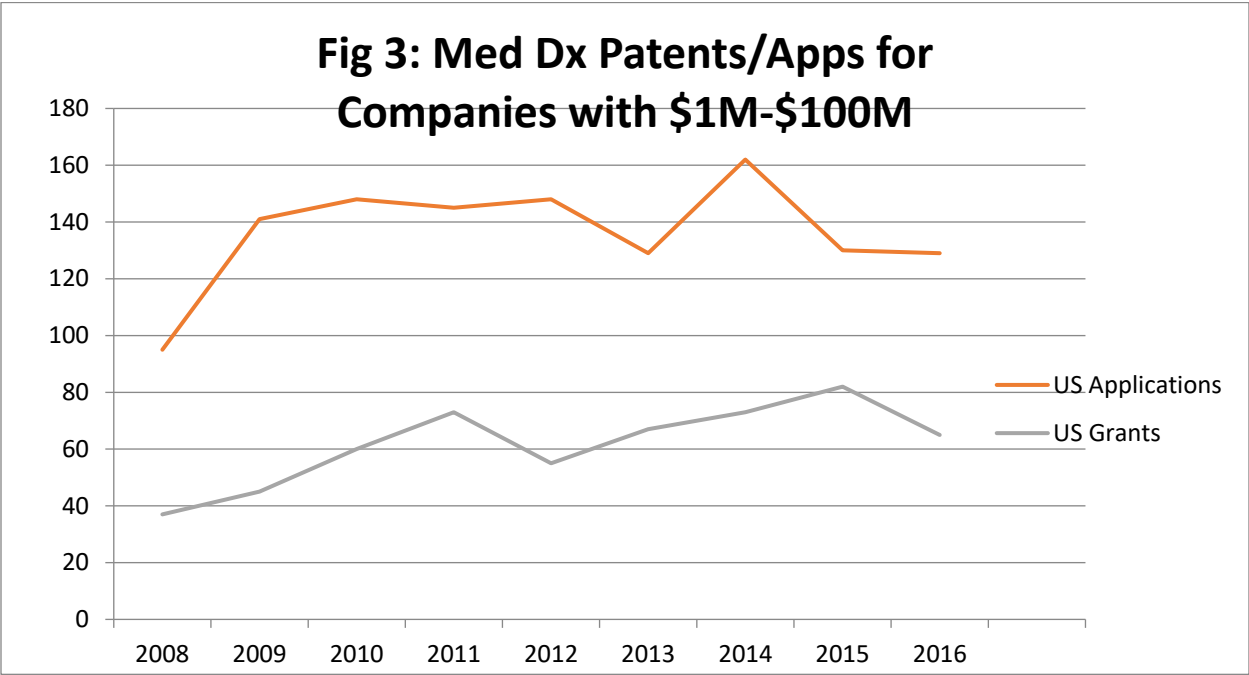
In this case, a rigorous event-study inquiry is challenging because of the difficulty of finding a control group and because insurance reimbursement changes and other factors have affected the diagnostic industry at the same time. Thus we cannot, at this stage, make causal claims. In addition, although we report grant data, we do not report whether claims were narrowed pursuant to *Mayo*.

With those caveats, our analysis indicates that diagnostic applications continued to be filed, and diagnostic patents granted, after the March 2012 decision. For example, Fig. 1 shows that the number of diagnostic applications published continued to grow from late 2013 through 2016. These applications were presumably all filed after March 2012. As for grants, those have also grown at a relatively steady pace since March 2012.



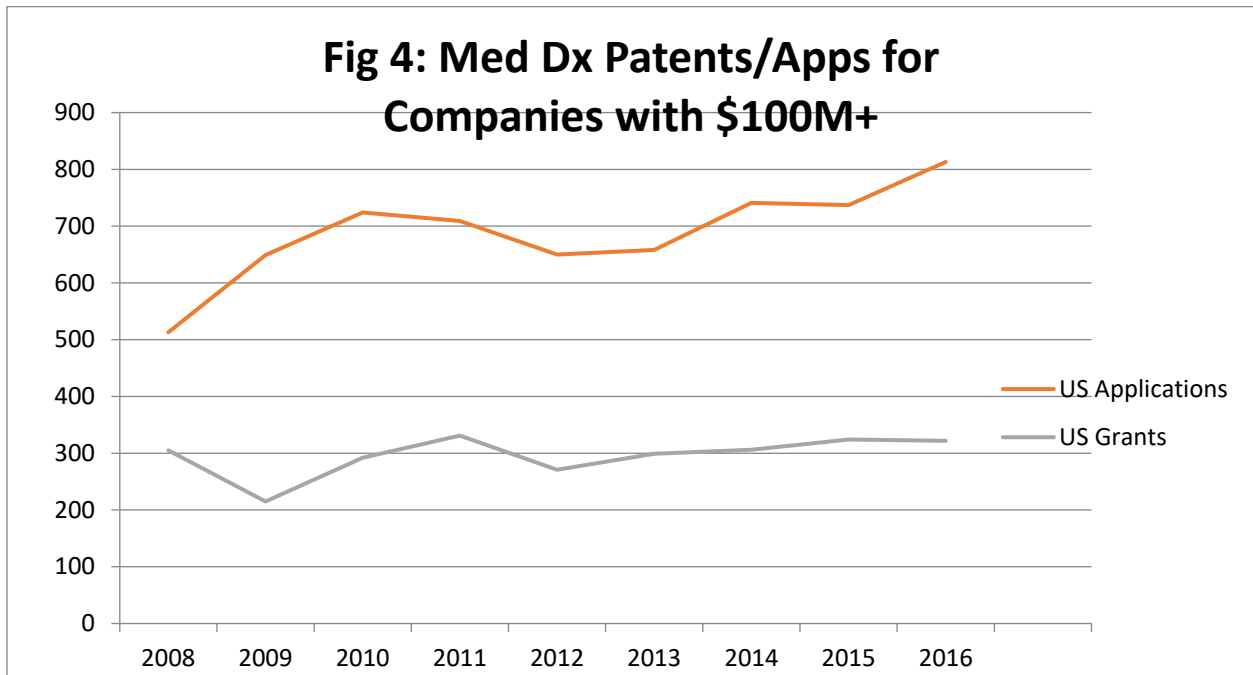


Growth across the industry has not been consistent, however. As Figure 2 shows, 69% of the applications published in 2016 were filed by firms with less than \$1 million in revenue. Our examination of the ownership of applications in this band suggests that a large percentage of the owners universities and other nonprofits. Similarly, these universities and other nonprofits have received steadily increasing patent grants. Strong governmental support for diagnostic medical research after the *Mayo* decision may have encouraged nonprofit filings.



In contrast, as Figure 3 shows, starting in mid to late 2013, published patent applications from firms with annual revenues between \$1 million and \$100 million declined. Firms in this range accounted for only 4% of applications published in 2016. By late 2014 patent grants to these firms had also declined although the absolute value of this decline was small and may reflect truncation bias due to non-publication requests (33 fewer applications were published in 2016 than 2014).

Finally, as Figure 4 shows, medium and large firms (with revenue over \$100M) showed slight growth in published applications and relatively flat issuances.



#### Appendix A

G01N2800: Detection or diagnosis of diseases (not including disease caused by micro-organisms where the micro-organism is detected)

G01N33/569 (detection of bacteria, viruses); G01N33/571 (detection of venereal disease); G01N33/574 (cancer detection)

C12Q1/6883 and C12Q1/6886 (using nucleic acids to test for disease)

C12Q2600/106, 112, and 118 (short nucleic acid sequences used for characterizing disease)