A HOLISTIC APPROACH TO COMPLEX MEDICAL DIAGNOSTICS

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Molecular diagnostic medicine is rapidly evolving from the reductionist study of individual biomarkers toward a systems approach that relies on increasingly sophisticated tools for generating, storing, and manipulating information. Researchers use laboratory tests, biosensors, scanners, medical records, and social media to obtain multiple layers of data and generate digitized profiles of subject populations. In the new era of cloud computing and whole genome sequencing, data collection is relatively cheap and easy. The core focus of contemporary research is on organizing and analyzing immense datasets and extracting meaningful information. But without structured commitments among research institutions, medical centers, and diagnostics companies to standardize and disclose collected data, a potential treasure trove of information could become irrevocably fragmented into proprietary silos. The policy challenge is to develop a legal framework that fosters data sharing among disparate parties that are not bound by strong reciprocity norms.

This presentation highlights the interplay between intellectual property and FDA regulation to advance a holistic approach to complex medical diagnostics. Recent Supreme Court decisions have created substantial uncertainty about the patent eligibility of scientific breakthroughs based on computer-implemented interrogation of large quantities of raw data. Heightened uncertainty surrounding the patentability of data-driven biomedical discoveries could undermine socially productive sharing regimes by inducing firms to rely more heavily on trade secrecy. But the IP system does not operate in a vacuum to govern information resources. Rising patent eligibility hurdles coincide with intensifying regulatory scrutiny of clinical diagnostics. The obvious concern is that the combination of an inability to obtain patents and higher regulatory barriers to market entry could decimate the fledgling industry supporting personalized medicine. However, perhaps counter-intuitively, a carefully crafted regulatory scheme actually could promote innovation by acting as a "visible hand" to coordinate the generation and dissemination of patent-ineligible diagnostic discoveries.

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