

*Minding the Template in Prometheus Laboratories:  
A Fuller Account of the Costs of Determine-and-Infer Claims*

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A number of recent cases at the Federal Circuit Court of Appeals have addressed whether correlation-based diagnostics in medical arts are patentable subject matter, and the Supreme Court has granted certiorari to consider the issue in *Prometheus Laboratories v. Mayo Collaborative Services*. One facet of most controversies over the reach of patentable subject matter is a relative welfare analysis: Is the marginal increment of patent protection at issue any less likely to promote technological progress than run-of-the-mill patent protection is? To date, the arguments addressing a relative welfare analysis of correlation-based diagnostics on both sides of the debate have framed the relevant increment of patent protection at issue in a narrow, art-specific fashion. The social value of the personalized medicine that these diagnostics enable, the economics of innovation in the biomedical sector, and the unique difficulties raised by patents that encompass the practice of medicine have been the standard fare of the debate.

This Article argues that a fuller account of the costs of a ruling in favor of a more expansive definition of patentable subject matter in *Prometheus Laboratories* can be achieved by breaking out of the narrow, art-specific nature of the contemporary debate. It is critical to mind the generic claim template that would be sanctioned by the more expansive definition: the *determine-and-infer* claim. Determine-and-infer claims follow a simple two-step template: (a) determining the value of a first variable using a prior-art technology and (b) mentally inferring the value of a second, correlated variable from a combination of the knowledge of the measured value of the first variable and a newly discovered correlation between the first and second variables. By focusing on this template, rather than solely on art-specific factors, two previously overlooked costs of sanctioning the patentability of correlation-based diagnostics come to the fore: *mental-process costs* and the *costs of off-label uses*.

Assuming that the limits of patentable subject matter should serve as a proxy for economic concerns, this Article also briefly notes some of the surprising doctrinal implications that follow from minding the template of the determine-and-infer claim.