

## **Limitations on the Scope of Biotechnology Patents**

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Biotechnology patents, particularly those relating to genes and genetic technologies, have raised a relatively high level of concern amongst those interested in legal and science policy. Many have speculated that these patents threaten to create patent thickets substantially impeding biomedical R&D and access to follow-on products and technology. One of the primary criticisms has been based on an assumption that gene-based patents are inordinately difficult to design around relative to other types of patents.

In this paper, I will review and discuss a variety of doctrinal limitations that will in many cases restrict the ability of biotechnology inventors to obtain effectively broad coverage of their inventions. This should, at least in some instances, attenuate some of the fears that have been expressed with respect to certain biotechnology patents. For example, recent litigations involving gene patents provide numerous examples where a putative infringer was able to circumvent seemingly broad patent claims by means of alternate technologies, or off-shoring of certain activities. In other cases, the courts have construed biotechnology patent claims in a manner much narrower than might have been supposed prior to the litigation, resulting in diminished effective claim scope. The enablement and written description requirements of section 112 can also impose substantial restrictions on biotechnology patent claim scope, as illustrated by a number of recent decisions in the courts and US patent office. Very recently the patent office has sought to reinvigorate the written description requirements as a distinct and substantial doctrinal limitation on biotechnology patent scope, as illustrated by their recent revision of the written description examination guidelines, and the Board of Patent Appeals and Interference decision in *Ex parte Kubin*. The Federal Circuit will have a chance to weigh in on the issue when it reviews *Kubin* later this year, and I will offer some thoughts on this important case.

After reviewing the many diverse limitations on the scope biotechnology patent claims, I will discuss some policy implications and important considerations for those working in biotechnology, as well as those concerned with crafting patent policy and doctrine that fosters and incentivizes biotechnological innovation.