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Mail Stop OPEA
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Dear Ms. Shaw:

In response to the USPTO's Request for Comments on Intellectual Property Enforcement in China, we provide the following anonymous remarks on behalf of a medium-sized biotechnology company. We welcome the opportunity provided by the USPTO to offer recommendations for improving the patent enforcement landscape in China.

Our experience has identified a variety of challenges that innovators face with China's patent enforcement systems.

1. Inconsistency of the State Intellectual Property Office of the P.R.C. ("SIPO") and courts in the interpretation of a "functional definition."

During the prosecution stage before SIPO, a "functional definition" is interpreted by SIPO as including all of the embodiments encompassed by the functional definition; but at the enforcement stage, a "functional definition" is interpreted by the court as being limited to those embodiments for which data is provided in the Examples set forth in the patent specification.

2. Narrow scope of granted claims.

The current practice before SIPO is to grant claims limited to exemplified embodiments. In the biotechnology arts, it was in the past routine to obtain claims before SIPO reciting "percent identity" or "percent homology" to a particular protein or DNA sequence. More recently, however, the expression of identity and/or homology (no matter how limiting the required percent identity or homology) has not been permitted.

3. Limitation on amendments.

During a patent invalidation trial, a patentee seeking to enforce a patent has only one opportunity to amend the claims before SIPO. However, any amendment must be limited to the specific elements recited in the claim set as originally granted, i.e. by deletion of claims, deletion of technical solutions or combination of technical solutions, regardless of the full scope of the patentee's disclosure.

4. Availability of doctrine of equivalents.

The availability and application of the doctrine of equivalents to claims in enforcement actions in China is at present unclear. This approach by the courts increases the risk to the innovator that a challenger might unfairly design around the claims and avoid liability for appropriating the innovator's invention.

5. Limitations on divisional filings.

Divisional applications before SIPO may only be filed during the pendency of the original national patent application, and therefore a patentee has little ability to adapt the scope of the claims to accommodate subsequent changes in patent practice or case law or unanticipated activity by infringers.