

# Patent Newsletter

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## PATENT PROSECUTION IN CHILE AND THE PRACTICE OF INAPI

### Biotech inventions - Definition of an Antibody

The Chilean Industrial Property Law recognizes the possibility of patenting biotech inventions, and a common objection in this kind of applications refers to the most appropriate manner of defining an antibody. Even though, this matter is not specifically addressed in the Law nor in the Regulations, in the case of patent application N° 3357-2007 the Examiner in charge articulated the position of INAPI indicating that: *“the correct and acceptable manner of describing an antibody is in terms of its CDRs (3 heavy chain CDRs and/or 3 light chain CDRs), or by the sequences of its variable regions (heavy and/or light chain variable region)”*.

It is therefore advisable to avoid definitions that center basically upon the functionality of the antibody, for they would most likely not be accepted by INAPI, forcing applicants to introduce changes to the application which will inevitably delay its grant.

### Grace Period Rules

According to the Grace Period rules, in the Chilean Industrial Property Law, those disclosures that have taken place up until 12 months before the application's date, and which originate in or derive from the applicant, or that are a consequence of acts of unfair competition against the applicant, will not be taken into account for novelty and inventive step purposes, provided they are specifically declared and evidenced at the time of filing the application. The practice of INAPI has been that of recognizing that foreign publications of counterparts of the invention can benefit from the Grace Period rules. It is important to bear in mind however, that applicants must specifically declare every single disclosure that had taken place within the 12 month-period prior to the filing, and not just only the most remote one.

In particular, if there are several foreign counterparts, divisional or



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continuations, sharing the same priority and which have been published at different dates within that 12 month-period, each of them must be declared and evidenced at the time of filing the application. If otherwise, those publications that are not declared will be taken into account in the novelty and inventive step analysis, irrespective of the fact that they may share the priority of another application duly declared and evidenced at the time of filing. Accordingly, the importance of a complete and thorough listing of every and all the disclosures at the time of invoking the Grace Period rules in Chile, can hardly be emphasized.

### LITIGATION

According to the Chilean Industrial Property Law, enforcement litigation is to be pursued before the Courts of Justice, while validity issues are the province of INAPI. Consequently patent litigation almost always tend to be two pronged, with the defendant in the infringement proceedings simultaneously challenging the validity of the asserted patent before INAPI.

In the case of patent 4803, which covers a remining process, the patentee, a natural person, sued a number of major mining companies including Codelco, a state-owned copper mining corporation. The Court declared the patent infringed and awarded damages in an amount exceeding USD 10 million, and this decision is currently under appeal. In parallel Codelco and Quebrada Blanca, one of the other mining companies that had been sued, had initiated cancellation actions against patent 4803 arguing that it lacked novelty because of earlier commercialization of the invention, and inventive step in view of an AU piece of prior art. Following the rules in the law, INAPI ordered the issuance of a technical report which was delivered last July 1st by a commission of experts recommending to accept the cancellation actions on both counts, i.e. lack of novelty and inventive step. Even though this is a technical opinion that can be traversed by the patentee, it certainly amounts as an important antecedent for INAPI's final decision.

A time will have to pass to see how this technical report will impact on the ongoing infringement litigation, however, it undeniably shows how difficult it can get for a Court to

progress in the resolution of an infringement case, when in parallel, and almost always in a different pace, INAPI can eventually turned down the very right that it has been asked to enforce.

### LEGISLATION

#### Trans Pacific Partnership (TPP), Negotiations

Multilateral negotiations to conclude the (TPP) have proven difficult in view of, among others, IP considerations, with the position of the US at least in Chile, originating most of the controversies. Indeed and in what refers to industrial property, Asilfa, the professional association that gathers local pharmaceutical companies, has voiced its concern over a series rules in the US proposal, which, they argue, would seriously impact in the ability to access medicines by the national population.

The concerns mainly circle around the data exclusivity and pharmaceutical linkage rules that would have been put forward by the US, and which would heighten the current Chilean standards. With respect to data exclusivity, US would be proposing to have it available to any pharmaceutical product for which submission of clinical data is required by the Health Agency to demonstrate its safety and efficacy, and not only for those pharmaceutical products that use a new chemical entity, as it is the situation under the current Law.

With respect to pharmaceutical linkage, US would be proposing to have it available to any product or use patents, and to include an automatic delay in the grant of the marketing approval of the generic product; meanwhile, in the linkage legislation project currently under study at the Chilean Congress, the option of linkage is restricted to active ingredient patents, and the delays in the grant of marketing approvals can only be implemented upon issuance of an specific judicial order.

The Agreement is expected to be concluded by the end of this year and close attention is to be placed in the outcome of the negotiations, for as seen, the final language in its IP chapter may require that Chile updates several of its current institutions in the patent and data exclusivity fields.