



Asociación Industrial de Laboratorios Farmacéuticos



April 2012

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Is An Automatic Delay Consistent With Equal Treatment?

TPP Provision

- Where a Party requires or permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence concerning safety or efficacy information for a product that was previously approved, such as evidence of prior marketing approval in another territory, each Party shall:

...

(b) unless such other person agrees to defer the marketing of the product until after the expiration of an identified patent, ensure that a patent holder may seek, prior to granting of marketing approval to an allegedly infringing product, available remedies by

providing:

(i) an **automatic delay** of the grant of marketing approval that remains in place for a period of time designed to ensure sufficient opportunity to adjudicate disputes concerning the validity or infringement of allegedly infringed patents;

Automatic Delay

- What is an “automatic delay”? : A non-merit based preliminary injunction.
- Are non-merit based preliminary injunctions the general rule? NO.

Some Info On Preliminary Injunctions

- “Injunction entered by a court prior to a final determination of the merits of a legal case, in order to restrain a party from going forward with a course of conduct ... until the case has been decided”
- Restrain Regulatory Agency from *granting marketing authorization* of the generic product during the patent infringement legal proceeding.

Requirements for P. Injunctions

- That there is a substantial likelihood of *success on the merits* of the case,
- That party seeking p. injunction faces a substantial threat of *irreparable damage or injury* if the injunction is not granted,
- That the *balance of harms* weighs in favor of the party seeking the p. injunction
- That the grant of an injunction would serve the public interest

Requirements for P. Injunctions

- *fumus boni iuris* (appearance of right) and *periculum in mora* (danger in delay)
- **Merit-based P. Injunctions:** Pharmaceutical Patent Holder should provide evidence to the Court that *prima facie*, there is an appearance of right (i.e. patent covering a pharmaceutical product will be infringed by the generic product) and danger of delay (loss of sales of innovative product).

Decision Based On The “Merits”

- Court have to look at the evidences (*merit*) provided by the party seeking the preliminary injunction and decide whether there is sufficient ground or not ... for blocking the marketing authorization of a generic product

Non-Merit Based P. Injunction

- Do not require the court to do said *merit assessment*: The injunction will be granted by the court only based on the copy of (i) the patent; (ii) evidence of having filed the patent with the health regulatory agency; and (iii) copy application for MA of the generic product.
- No technical opinion on the possible infringement is required.

Preliminary Conclusion

- Non-merit based P. Injunction (Automatic Delay) it's a more easy way to obtain the injunction since the court will be obliged to grant it if said documents are provided.
- The court do not have discretion to grant it or not.

Preliminary Conclusion

- Non-merit based p. injunction (automatic delay) is a *more favorable* regulation only applicable for a specific group:
Pharmaceutical Patent Holders

Equal Treatment

- Equal treatment requires that comparable situations are not treated differently and that different situations are not treated similarly unless such a difference or similarity in treatment can be rationally and *objectively justified*

Equal Treatment

- What's the *rational* and *objective justification* for treating Pharmaceutical Patent Holder in a more favorable (different) way compared to other Patent Holders or other persons or groups of persons?
- Only to the extent *rational* and *objective justification* can be provided an automatic delay will be consistent with equal treatment.

Equal Treatment

- Why should Pharmaceutical Patent Holders be treated in a more favorable way providing them automatic delay?
- Are Pharmaceutical Patent Holders a group that tends to be weak and requires special support?

Equal Treatment

- Are we talking here about small and medium-sized companies?
- Providing *rational* and *objective* justification for this special treatment in favor of pharmaceutical patent holders tends to be difficult ...

Final Remarks

- Since it seems that there is a constitutional issue with automatic delays, can a Government commit to implement it without doing legal assessments?

Thank you!

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