

The Patent Lawyer

July / August 2020

GLOBAL REACH, LOCAL KNOWLEDGE

www.patentlawyermagazine.com

Is this really the end of Brazil's patent backlog?



Launch

interactive document

Joaquim Eugenio Goulart and Bernardo Marinho Fontes Alexandre of Danneman Siemsen discuss the country's recent efforts



2020 AIPPI World Congress:
Online... Extended... Free!



The AIPPI World Congress goes virtual from October 5 to 14, 2020—and it's free for all 9,000 AIPPI members!

AIPPI is proud to release the first details of the 2020 AIPPI World Congress Online. Participation is completely FREE for all AIPPI members. It promises to be the largest event AIPPI has ever held!

The Congress going virtual has lots of advantages for you:

- 8 days of high profile educational content.
- You can be there when the famous AIPPI Resolutions to harmonize international IP law are drafted.
- Be part of the audience as hot topics are discussed by expert panels.
- Connect online with peers from 120+ countries.
- Enjoy all of your Congress favourites – and expect some new additions to the programme!
- No matter where you are in the world, you will be able to find something of interest at a time that suits you
- And remember, all of this is offered to AIPPI members at no additional cost!

Mark your diaries for this unforgettable AIPPI World Congress Online from October 5 to 14, 2020. Registration opens on September 9, 2020.

P.S. If a non-member wants to join the online Congress they can do so by becoming an AIPPI member. They can either join AIPPI in the normal way on the AIPPI website, or use the upcoming "Join and Register" service for 200 Swiss Francs.

Non-members who just want to join the online Congress can register for 400 Swiss Francs.

AIPPI (International Association for the Protection of Intellectual Property)
www.aippi.org



Positive declaratory proceedings in Italy

Giancarlo Del Corno and Francesca La Rocca of Studio Legale Sena e Tarchini discuss how such proceedings can be used to act upon and prevent infringement.

One of the issues often faced in patent litigation is the timing of relative infringement proceedings, especially when the possible infringement has not yet appeared on the market, yet the patent holder already has (or may have) sufficient evidence that such behavior will soon occur.

Such an issue becomes more sensitive when taking into consideration that sometimes the requirement of urgency is fundamental for the granting of a preliminary injunction, and in the so-called "sakes of interests" the tolerance of the patent holder may play role against him in any interim measure.

Moreover, always in the balance of interests in interim proceedings, the circumstance that the possible interfering product is already on the market and that the possible infringer may affirm that he was (rightly or wrongly) in good faith in believing that such behavior did not conflict with any third party's rights may work against the holder of the patent.

In this situation, one possible option may be the dispatch of a cease and desist letter.

However, such a letter usually presents some cons, such as the likely reaction by the alleged infringer, consisting in the launch of revocation/nullity proceedings, which, at least in the Italian experience, may deprive the patent holder of the choice of Court to be seized for any future infringement proceedings (which the Italian practice teaches to be rather important for the positive outcome of such litigation) and, moreover, renders more difficult the granting of preliminary injunctions due to the fact that the existence of a revocation/nullity litigation determines the failure of presumption of validity of the patent.

Furthermore, at least for the Italian practice, the role of plaintiff in a Court litigation determines some advantages that are useful to keep in your hands, rather than leaving to the counterpart.

Another possible (and preferable) option is the institution of declaratory proceedings.



Francesca La Rocca



Giancarlo Del Corno

Declaratory proceedings are proceedings in which the plaintiff demands that the possible future behavior of the defendant would represent a breach of a right if performed with certain modalities and/or over a certain period of time.

In other words, the plaintiff asks the Court to make an injunction in consideration of a future episode - i.e. of the possibility that there will occur an unlawful behavior - and therefore a damage will be provoked, in the absence of a precise undertaking by the potential infringer to avoid such behavior.

These types of proceedings are useful in intellectual property litigation to promptly react every time the counterpart starts performing preparatory acts of a later use, which proves the existence of the risk of a future violation of an intellectual property right.

The demand of this declaratory proceedings is drafted as follows: "ascertain and declare the possible manufacture, sale, offer for sale, advertise by the defendant if performed prior to 'zz' (date of expiry of the relevant intellectual property rights) represents infringement of the intellectual property right n. ...".

These proceedings are aimed at getting an injunction which in some way corresponds to the injunction given by the High Court in the case *Merck, Sharp & Dohme Corp. and Bristol*

Résumés

Francesca La Rocca

Francesca joined Studio Legale Sena e Tarchini in 2012. She deals with litigation and with consultancy and extrajudicial activities. In the last few years, she has been involved in several pan-European litigations regarding patent law.

Giancarlo Del Corno

Giancarlo joined Studio Legale Sena e Tarchini in 1985. He is an excellent patent litigator with significant experience handling complex world-wide IP disputes, especially in the pharmaceutical industry.



*Myers Squibb
Pharmaceuticals Ltd v
Teva Pharma B.V. and Teva
UK Ltd.*

In Italy, the practice of the so-called "declaratory infringement proceedings" was developed by our law firm, Sena e Tarchini, ten years ago, as a reply to the no infringement declaratory proceedings commonly used by generic/biosimilar companies.

The first case where such proceedings were started in Italy regarded the exercise of a patent right against some generic companies who had filed an application for the marketing authorizations for the placing in commerce of generic medicines long before the expiry of patent protection.

Indeed, the filing of such applications occurred more than four years prior to the expiry of the patent protection, and it was argued that such conduct was a precise indication of the intent of the defendants to start an activity of manufacture and/or importation and/or commercialization of the medicines in question without waiting for the expiry of the industrial property rights.

At the time, it was discussed whether the demands, having as subject matter the declaration of the lawfulness/unlawfulness of a future activity, would be considered admissible by the Italian system, or whether only the demands having as subject matter a conduct already in course were allowed.

Instead, it was always entirely undisputed that declaratory demands are admitted by the Italian system, and there was no doubt whatsoever about the admissibility of the declaratory demands of no infringement.

In this context we argued that there was no valid reason to question the possibility of advance demands for "positive" declaration of the threat of infringement.

The main problem for declaratory infringement proceedings is the question of existence of standing to sue, and of the capacity to be sued.

Theoretically, these demands are admissible under Italian law if there are sufficient indications prior to any concrete realization that a specified behavior will be carried out.

Pragmatically, the Italian case law is unanimous in retaining as admissible proceedings for the declaration on a future activity if the two following conditions are met: there is an objective and tangible uncertainty; and the plaintiff suffers a damage following such juridical uncertainty, which is substantiated not only in the present damage of a right, but also in the risk of a future damage.

Therefore, to legitimize and ground the institution of these kinds of proceedings, plaintiffs should show relevant and concordant circumstantial evidence which confirms their fear.

These types of proceedings are often started in pharmaceutical patent litigations against

“
It was discussed whether the demands would be considered admissible by the Italian system.
”

generic/biosimilar companies when the originator fears the entrance into the market of the generic/biosimilar medicine prior the expiry of the patent.

In this type of dispute, the most important element of proof is represented by the defendants' refusal to commit themselves to acknowledge the validity of the intellectual property right at issue and, accordingly, to refrain from manufacturing and commercializing in Italy generic/biosimilar medicines containing the same active ingredient of the patent. Indeed, such behavior confirms the originator's fear and legitimizes the commencement of positive declaratory proceedings.

Therefore, the lack of a precise commitment by the defendant not to carry out a specific behavior (i.e. the anticipated launch of the infringing product) could represent a strong indication together with others (such as an anticipated filing of the marketing authorization application, the launch of the generic product in a foreign market, or the institution of nullity/revocation proceedings in other jurisdictions) to legitimize and ground the institution such proceedings.

In our opinion, the best strategy in such types of litigation, which we have successfully followed in the past, is to send a message to the generic/biosimilar companies explicitly mentioning the existence of the patent and expressly stating the willingness to protect the intellectual property rights.

Even if often the generic companies do not reply to such letters, this strategy is advisable not only to legitimize and ground the institution of positive declaratory proceedings, but also because sometimes the Judges are reluctant to grant preliminary injunctions if the generic companies have completed all the regulatory steps and the product is near to be launched, without being warned in advance.

Furthermore, to Italian law there are no disadvantages in pursuing this step.

In the event that the counterparts do not take an express commitment to respect the claimed intellectual property right, and as said generic/biosimilar companies do usually follow such a policy, a positive declaratory proceeding may be instituted.

Once the litigation is started, if the generic company appears before the Court stating that they are not interested in launching the product prior to the expiry date, then the patent owner is entitled to ask for a formal engagement; if, on the contrary, the generic company does not make this statement, this sounds like an implied admission that they are interested in launching the product prior to the expiry date, and this confirms the patent owner's interest in

“
The lack of a commitment by the defendant not to carry out a specific behavior could represent a strong indication to legitimize such proceedings.
”

instituting the proceedings.

Positive declaratory proceedings are a useful judicial means for the intellectual property owner to immediately react prior to the concrete realization of the infringement of their right; however, before starting an action, the case should adequately and carefully instructed.

Contact

Studio Legale Sena e Tarchini

20121 Milan - Corso Venezia n. 2

Tel: 0276000579

Fax: 02782097

75008 Paris - 30, rue d'Astorg

Tel: 0147637475

Fax: 0146223327

senatarchini@senatarchini.com

www.senatarchini.com