CORONAVIRUS
OVERCOMING THE DIFFICULTIES

COVID-19 MEASURES ON LITIGATION. FOCUS ON IP AND PHARMA PROCEEDINGS

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In these extraordinary days when everything is affected by the COVID-19 emergency, one of the first decisions taken by the Italian Government addressed the judicial system and provided the **stay of almost all civil proceedings**, postponing hearings until after **April 15, 2020** and suspending deadlines for filing briefs and procedural activities in general until the same date.

This provision is laid down in Article 83 of Decree Law no. 18 of 17 March 2020 - the so-called *Cura Italia* Decree (***Care Italy* Decree**) - which is in force, and repealed Article 1 of Decree Law no. 11 of 8 March 2020. Under the latter provision, the postponement of hearings and suspension of deadlines had been set until March 22, 2020.

Moreover, since the *Care Italy* Decree already contains the **possibility to yet postpone** adjournment dates, it is highly likely that suspensions and postponements will be further extended at least to the end of June 2020. The aforesaid Article 83 of the Decree (which repeals the analogous Article 2 of Decree Law no. 11 of 8 March 2020) specifies that for the period from April 16 to June 30, 2020, the Heads of Judicial Offices shall adopt the necessary organizational measures in order to prevent the physical gathering of pluralities of attendees people inside hearing rooms and premises open to the public and, in any event, close contacts among persons.

The net outcome of these suspensions and postponements is likely to be, at the end of the day, a **paralysis of the Italian judicial system** for almost the entirety of 2020. Many hearings falling within the relevant period have already been postponed by more than two months and, in some cases, also by as long as one year.

It is worthwhile noting that, whilst the key-reason for the postponement of hearings is the present lack of implementation rules that allow the attendance to hearings via web (and thus to avoid the physical “gathering of people”, as it normally happens at ordinary hearings), there seems to be **no reason for an equal suspension of deadlines** for the filing briefs and other procedural accomplishments, since all Italian Courts have implemented electronic filing since years.

However, one can also see the bright side of things. Ultimately, the *Care Italy* Decree is **good for lawyers and Judges**, inasmuch it allows, in particular after April 15, to schedule web hearings and/or replace actual hearings by exchanges of briefs and adjudicate cases only based on the written phase. In this way, there might be no need for the Government to further postpone hearings

until after June 2020 or, even worse, later in time. This is true for at least the majority of hearings, for which the attendance of parties and witnesses is not required.

However, the suspensions and postponements outlined above do not cover all civil proceedings. In particular, proceedings concerning (inter alia) minors, interdiction and incapacitation, suspension of the enforceability of first and second instance judgements, as well as interim proceedings related to fundamental rights remain in any event outside their scope.

Conversely, disputes relating to **corporate, commercial and IP cases** (in a nutshell, all actions that concern the regular functioning of the Italian economy) are frozen without exception.

There is, though, a general provision that excludes from the suspensions and postponements "*all proceedings in which the delay in handling the case could cause serious harm to the parties*" (see again Article 83 of the *Care Italy* Decree). However, the Legislator so far provided no guidance as to how the expression "*serious harm"* should be construed; it is, in particular, unclear if such harm could be just economic damage, or rather a prejudice uncapable or remedying by financial compensatione.

In a different perspective, whilst the procedural scenarios highlighted above could fit for the activities and industries that have been locked down by the Decree of the President of the Council of Ministers dated 22 March 2020 - the so called Decreto *Chiudi Italia* (***Shutdown Italy*** **Decree**) - it cannot work for activities and industries which remain operational because they are essential for the functioning of the country, albeit at a reduced pace and according to a priority inspired model (such as transports, healthcare, pharma, food supply chain, etc.).

Annex 1 to the *Shutdown Italy* Decree in facts lists specific activities that do not fall within the perimeter of the lockdown, and one of them is indeed the **manufacture of basic pharmaceutical products** and pharmaceutical preparations, as well as medical and dental instruments, devices and supplies. Moreover, Article 1, letter f), expressly specifies that the manufacturing, transportation, commercialization and delivery of medicines, sanitary technology and medical-surgical devices is always allowed, as activities that are verily functional to coping with the emergency.

The stay for practical purposes of judicial activities may result in significant "side effects" in particular for **pharmaceutical patent litigation**.

A first consequence is that companies that commercialize medicines in breach of product or process patents belonging to third parties will be more inclined to **continue their infringing activities** because the judicial sanction has become less certain and less timely. Mirror-wise, patentees are more likely to be left with fewer and less effective remedies. The further result downstream of this unfortunate combination of circumstances is that **R&D investments will be objectively less encouraged** at a time when new research is most needed to develop new drugs to fight the Covid-19 pandemic and treat a whole array of patients and conditions that revolve around the extraordinary situation we are all confronted with.

It is common ground that **time is a key-factor** in the protection of IP rights. The very nature of infringement very often requires a quick and effective intervention, because if the infringer protracts its unlawful conduct for too long, the prejudice suffered by the right holder could prove beyond recovery. In particular, the **lost profit** connected with the diversion of customers and market shares to an illegitimate competitor can be **extremely difficult to quantify retrospectively**.

This is true in particular if the matter in dispute concerns a medicine qualifying for reimbursement from the National Health Service, in circumstances where an originator medicine undergoes a **significant reduction in price** because an infringing generic version of the same medicine is sold at a much lower price. Actually, in order not to lose excessive market shares, the patentee will be

forced in practice to substantially align its price to the **lowest price of the reimbursed generic medicine**. Within a single month, the total loss of profit caused by the infringement may rocket up to millions of Euros. Hence, the patentee would need to **file proceedings as soon as possible**, in order to obtain at least a *prima facie* finding of the infringement, and a preliminary injunction against the infringer. Even if the patentee is ultimately successful in the merit action, which could be years down the road, this will be no remedy, since reimbursed prices can go down, but never go up again. For that reason, compensation of damages is by definition no adequate remedy.

For that reason, right holders usually apply for ***interim* measures**, especially preliminary injunctions, providing evidence of the fulfilment of two cumulative requirements: *fumus boni iuris* (the likelihood of the existence of a valid IP right) and ***periculum in mora***, which consists of the imminent risk of serious and irreparable harm caused by the continuation of the infringement during the time required by ordinary proceedings. According to Article 131 of the Industrial Property Code, the owner of an IP right may apply for an injunction against any imminent infringement of his right and the prosecution or repetition of any ongoing infringement.

Therefore, coming back to the newly introduces provisions that exclude the stay of "*all proceedings in which the delay in handling the case could cause serious harm to the parties*" it will of cardinal importance to understand whether IP (at least pharma patent) litigation involving the grant of *interim* measures ultimately **falls within its scope**.

In the abstract, in a strictly legal perspective **proceedings concerning the violation of a pharmaceutical patent right** might be included among those in which the delayed handling of the case could cause serious harm, considering that the injury suffered by the originator due to the infringement cannot be entirely recovered through money compensation.

However, especially in these days of sanitary emergency, the protection of IP rights will need to be balanced with Article 32 of the Italian Constitution, which enshrines the **fundamental right to health** of each human being. Furthermore, a different treatment of patent actions and proceedings dependent on the object of the patent might involves additional constitutional issues from the angle of the principle of equality (Article 3) and the TRIPS Agreement. Therefore, there is a concrete likelihood that an application for *interim* measures concerning the infringement of a pharmaceutical patent or SPC would be dismissed upfront, also in light of the fact that the courts could consider subsequent money compensation adequate under the circumstances, especially in the presence of a solvent defendant.

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