INTELLECTUAL PROPERTY & HEALTH

News to know

FRANCE & EUROPE – September 2021

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INTRODUCTION

Coinciding with the arrival of Claire Boosz in our Intellectual Property team, we are delighted to launch the first issue of our Newsletter dedicated to Intellectual Property in the health sector, in synergy with our Life Sciences team, composed of Emmanuelle Trombe, Anthony Paronneau, Anne-France Moreau and Katya Ascher.

Pharmaceutical laboratories, biotechs, food supplements and dietary products professionals, cosmetics companies and medical devices manufacturers, this newsletter is for you!

You will discover the legal and jurisprudential news in patent law, trademark law and other IP rights, in your sector only.

Enjoy your reading and see you soon for a new selection!

The McDermott Will & Emery Intellectual Property team

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NEWS

DRAFT LAW - FIGHT AGAINST COUNTERFEITING - INTERNET - CUSTOMS POWERS

On June 15, 2021, a bill to modernize the fight against counterfeiting (No. 4246) was tabled in the French National Assembly. Some of the provisions, in particular its Articles 11 and 15, aim to more effectively combat counterfeit medicines.

By adding two new articles to the French Public Health Code, Article 11 would allow the French National Agency for the Safety of Medicines and Health Products ("**ANSM**") to:

- in addition to a decision to suspend or prohibit an activity taken in application of Article L. 5312-1 of the French Public Health Code (a "sanitary police decision"), pronounce a decision to suspend access to the Internet site through which the activity is conducted;
- send a copy of the suspension decision to any website intermediary and provide them with formal notice to prevent access;
- request the Internet service providers and hosts, when an enforceable court decision has prohibited access to an Internet site the content of which falls within the scope of Articles L. 5421-2 and L. 5421-13 of the French Public Health Code, to prevent access to any "*mirror*" website (a website with identical or equivalent content);
- request all search engine operator to take all necessary measures to prevent the communication of URLs proving access to the "*mirror*" website.

By amending Article 67 bis-1 of the French Customs Code, Article 15 would extend customs powers by allowing the purchase of the counterfeit goods or falsified medicines, as is currently the case for narcotic products.

PATENTS

APPLICATION FOR INTERIM MEASURES - COUNTERCLAIM FOR PATENT INVALIDITY - INVENTIVE STEP - PLAUSIBILITY OF THE INVENTION

TJ Paris [Judicial Court of Paris], May 12, 2021, Sanofi v. Teva (No. RG 21/53136)

The Court found the defendant's arguments to be sufficiently serious to call into question the apparent validity of the asserted patent and to reject plaintiff's request for interim measures.

The Sanofi group manufactures and markets, under the name "*Jevtana*", a drug containing cabazitaxel for the treatment of metastatic castration-resistant prostate cancer. A European patent EP 2 493 466 entitled "*Novel antitumor use of cabazitaxel*", based on an international application filed on October 27, 2010, was filed and subsequently granted.

On August 19, 2020, the Teva group obtained a marketing authorization for its hybrid product "*Cabazitaxel - Teva Santé*" under the so-called "*abridged"* procedure, which allows reference to the results of preclinical and clinical trials conducted for the reference product. Teva Santé declared marketing this product since March 23, 2021. Sanofi group filed an application, claiming that its rights were likely to be infringed and requesting interim measures prohibiting and recalling the hybrid product concerned.

The Court reiterated that the court, in deciding whether to grant interim measures, must assess the

seriousness of the defense arguments presented, such as the validity of the patent and the materiality of the infringement, and evaluate the proportionality between the contestation of the alleged infringement and the provisional measures requested, considering the stakes in dispute - which are economic but also of public health - and the risks incurred by each of the parties.

The Court noted that, in order to challenge the validity of Sanofi's patent and its inventive step, Teva Santé does not rely on the disclosure of a clinical trial, but rather on the expectation of what this trial could generate in the light of the available data and its interpretation. By contrast Sanofi argued that, at the date of priority, there was no reasonable hope of success for the therapeutic indication. A response in a single patient in a Phase I trial and the absence of a Phase II trial made the positive results of the clinical trial particularly unpredictable.

The Court observed that, as of the priority date, the results of the clinical trials in progress were expected and considered that the information contained in the study was relevant; even though it was a Phase I trial, it indicated encouraging results. The Court found that Teva Santé rightly relied on a context that can be analyzed as giving rise to a reasonable hope of success with regard to all the effects claimed in the patent. In so doing, the Court found that the publication of the protocol of a clinical trial without results should be considered in the assessment of inventive step and thus found the defendant's arguments based on the absence of inventive step to be sufficiently serious to not justify the granting of the requested interim measures.

APPLICATION FOR INTERIM MEASURES - DISTRIBUTOR'S STANDING TO SUE - LACK OF INVENTIVE STEP - LIKELIHOOD OF INFRINGEMENT

CA Paris [Paris Court of Appeal], June 15, 2021, Allergan v. Mylan (N°RG 20/12617)

The Court, after observing the existence of a serious dispute as to the likelihood of infringement, affirmed the interim order of the President of the Paris Court of First Instance, ruling that there was no need to issue an interim injunctions.

In 2020, Allergan Inc., and Allergan France - holder of the European patent EP 1 753 434 designating France, entitled "*Improved bimatoprost ophthalmic solution",* and distributor in France of the product Lumigan 0.1mg/ml implementing the EP 434 patent, - sued Mylan, which had obtained a marketing authorization and marketed a product called "*Bimatoprost MylanPharma 0.1 mg/ml, collyrium solution*".

As an initial matter, the Court recalled that courts may on an application for interim relief order the recall of allegedly infringing products and their withdrawal from commercial channels, including the recall of products sold through third parties, such as pharmacies.

The Court then held that Allergan France, in its capacity as a distributor of the medicinal product implementing patent EP 434, was entitled to bring an action jointly with Allergan Inc, the owner of the patent, even in the absence of a formal license granting it such right. The Court observed that, in accordance with Article 4(b) of Directive 2004/48/EC of April 29, 2004, "*all other persons authorized to use intellectual property rights, in particular licensees*" have the right to request the

application of measures, procedures and remedies for infringement of intellectual property rights. Pursuant to Articles L. 615-2 and L. 615-3 of the French Intellectual Property Code, interpreted in light of the Directive, Allergan France, which exploits the Lumigan 0.1mg/ml MA in France with the agreement of the patent holder, had standing to sue jointly with the patent owner.

Finally, the Court reiterated that courts considering an application for interim relief must rule on defenses, including when these relate to the validity of the patent. In this case, considering the defense of lack of inventive step, the Court noted that technical problem to be resolved consisted of improving the formulation of the closest prior art (Lumigan 0.3 mg/ml) in order to maintain its effectiveness, while reducing its side effects, namely the high risk of conjunctival hyperemia. The difference between EP 434 and Lumigan 0.3 mg/ml was the concentration of bimatoprost and BAK. The Court concluded that a person skilled in the art would not be dissuaded from adjusting the doses of bimatoprost and BAK, by reducing the concentration of bimatoprost in order to limit the undesirable effects and by compensating for this reduction by increasing the concentration of BAK. The Court thus concluded that the defense that the EP 434 lacked the inventive step appeared to be a serious means of contesting the likelihood of infringement and consequently, rejected Allergan's application for interim measures of injunction and recall of the products.

TRADEMARKS

DRUG TRADEMARK - DAMAGE TO REPUTATION - INVALIDITY AND PROHIBITION BY HEALTH AUTHORITIES

Cass. com. [Commercial Court of the Court of Cassation], May 27, 2021, Boehringer (formerly Merial) v. Virbac and Alfamed (Appeal No. F 19-17.676)

The Court overturned the appellate decision in part and ruled that the admissibility of an action for cancellation of a drug trademark is not conditional on the prior prohibition of the trademark by the health authorities.

Boehringer Ingelheim Animal Health France (formerly Merial), a pharmaceutical company marketing medicines for animals, is the owner of the trademark "*Frontline"*, under which it markets an antiparasitic product based on an active ingredient called "*fipronil*".

When the patent covering "*fipronil*" fell into the public domain, the company Virbac marketed, under the brand name "*Fiproline*", an antiparasitic for dogs and cats based on the same active ingredient, manufactured by the company Alfamed.

In 2011, Merial sued Virbac and Alfamed for:

- payment of damages for harming the reputation of its trademark "*Frontline*", based on Article L. 713-5 of the French Intellectual Property Code; and
- cancellation of the trademark "*Fiproline"* based on Articles L. 711-3, b) of the French Intellectual Property Code (pursuant to which a trademark whose use is legally prohibited must be declared null and void) and R. 5141-1-1 of the French Public Health Code (pursuant to which, when the name of a veterinary medicinal product is an invented name, it must not be confused with the common name)

With respect to the harm caused to the reputation of the "*Frontline"* trademark, the Court recalled that the use of a sign that bears no similarity to another trademark could not take unfair advantage of, or be detrimental to, the distinctive character or reputation

of such other trademark, within the meaning of Article L. 713-5 of the French Intellectual Property Code in its previous version. The Court affirmed the decision of the Court of Appeals, rejecting the claim that the use of "*Fiproline"* trademark caused harm to the reputation of *"Frontline"* trademark, without examining the reputation of the "*Frontline"* trademark, having found no similarity between the "*Frontline"* and "*Fiproline"* trademarks.

With respect to the cancellation of the trademark "*Fiproline"*, the Court overturned the appellate decision which, in rejecting Boehringer's request for cancellation, had held that, in the absence of a prohibition on use by the health authorities, the trademark "*Fiproline"* could not be considered contrary to public policy, and had held that Boehringer could not rely on the combined provisions of the above-mentioned articles. The Court clarifies this point. There is no need for a prior prohibition by a health authority to invoke the invalidity of a trademark based on the combination of Articles L. 711-3, b) of the French Intellectual Property Code and R. 5141-1-1 of the French Public Health Code.

VALIDITY OF THE TRADEMARK - LACK OF DISTINCTIVE CHARACTER - LATIN TERMS - DESCRIPTIVE CHARACTER

Cass. com. [Commercial Court of the Court of Cassation], June 23, 2021, Compagnie Générale de Diététique (CGD) v. Clavis (Appeal n°W 18-20.170)

The Court overturned the decision of the Paris Court of Appeal which had cancelled the French and European Union word trademarks "*Garum*" and "*Garum armoricum*", owned by CGD.

CGD manufactures and markets food supplements and dietary products, including a food supplement with beneficial effects for memory, concentration and psycho-emotional balance, under the trademarks "*Garum*" and "*Garum armoricum*". In 2011, it sued the Italian company Clavis for trademark infringement for having used these trademarks by declaring that its dietary supplement, called "*Clavis Harmoniae*", contains magnesium and "*garum armoricum*" or "*garum sociorum exquisitus*", which is the Latin name for an extract of fish viscera hydrolized by autolysis and then dried.

Clavis sought to invalidate the trademarks "*Garum*" and "*Garum armoricum*" for lack of distinctive character. French judges declared these trademarks invalid, holding that the term "*garum*" serves to designate a component of the product and that the term "*armoricum*" - which evokes Brittany - serves to designate its geographical origin.

CGD appealed. The Court overturned the decision of the Paris Court of Appeal based on Article L. 711-2 of the French Intellectual Property Code (as previously drafted) and Article 7(1)(c) of Regulation (EC) No 40/94 on the Community trademark. It held that a trademark must be refused registration if, on the date of its filing, it constitutes, for the interested parties, a description of the characteristics of the goods or services concerned or if it is reasonable to expect that this will be the case in the future.

In support of its decision finding the trademarks descriptive and thus invalid the Paris Court of Appeal - which had nevertheless noted that the definition of "*garum*" was not included in medical and pharmaceutical dictionaries and that the awareness study carried out at CGD's request showed that only 3% of pharmacists questioned and 2% of the public knew the term - relied on the fact that the term "*garum"* could be used to designate the actual characteristic of the products and that the combination of the terms "*garum*" and "*armoricum*" would be understood as designating garum from Brittany.

Thus the Court overturned the decision of the Court of Appeal, on the basis that it had erred in not finding that on the date the trademarks were filed, they would be perceived as descriptive of the goods in question or of one of their characteristics or that it would be reasonable to expect that this would be the case in the future.

VALIDITY OF THE TRADEMARK - BAD FAITH REGISTRATION - COLOR SHADE OR SHAPE OF PRODUCT IN COLOR - PATENT EXPIRATION

CA Paris [Paris Court of Appeal], June 25, 2021, Ceramtec GmbH v. Coorstek Bioceramics LLC (No. RG 18/15306)

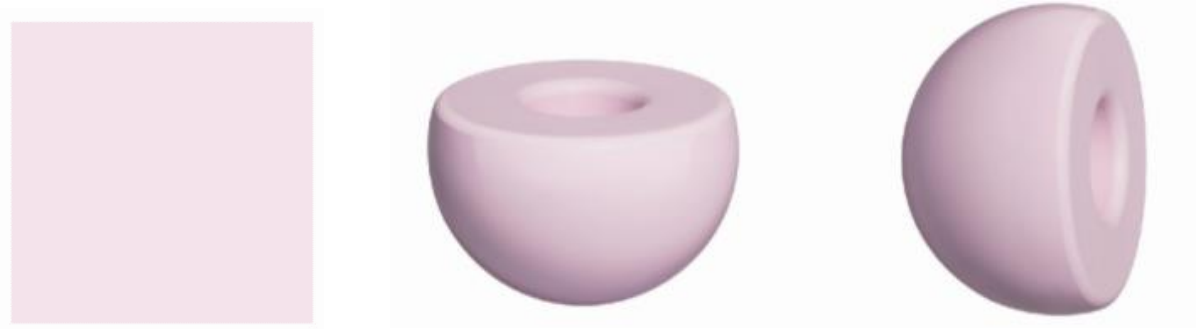
The Paris Court of Appeal affirmed the cancellation of the European Union trademarks consisting of the color pink (pantone pink 677C 2010 edition) and the shape of a pink ball, filed a few days after the expiration of a patent, on the basis that they were filed in bad faith.

The German company Ceramtec specializes in the development, manufacture and distribution of technical ceramic components, which it sells to prosthesis manufacturers for use in hips or knees implants. It held European patent EP 0 542 815 designating France, relating to a ceramic composite material, which expired on August 5, 2011. On August 23, 2011, it filed three European Union trademark applications, one corresponding to the pink color of its ceramic material, the other two representing the spherical shape of the upper part of the hip joint ball with a centered cylindrical hole.

In 2013, Ceramtec sued Coorsteck, a US company, for infringement of its trademarks and passing off for copying the characteristic pink color of its products. As a counterclaim, Coorsteck requested the finding of invalidity of Ceramtec's trademarks on the grounds that they had been filed in bad faith.

The Court explained that, in order to assess the applicant's bad faith, the applicant's intention at the date of filing the application for registration must be taken into consideration. In accordance with the Court of Justice of the European Union's jurisprudence, a trademark is invalid on the basis of filing in bad faith where it is apparent from relevant and corroborating evidence that the proprietor filed an application for registration not with the aim of participating, in a fair manner, in market competition, but with the intention of damaging the interests of third parties in a manner which is not in accordance with honest practices, or with the intention of obtaining an exclusive right for purposes other than those relating to the functions of a trademark, in particular, the essential function of indication of origin. The Court further explained that any allegation of bad faith must be assessed globally, taking into account all the relevant factual circumstances of the case.

In this case, the Court found that the nature of the trademarks applied for (a shade of color or the shape of a colored product) and whether that color is due to a technical characteristic of the material covered



by a patent must be taken into account. In fact, the pink color of Ceramtec's prosthetic components is due to the presence of chromium oxide in the composition of the material, and at the time the trademarks were filed, Ceramtec had asserted in communications that the addition of chromium oxide had a technical effect and contributed to the hardness and strength of the material subject to its patent. The pink color was therefore not perceived by Ceramtec as an arbitrary element or a sign to attract customers, but as the consequence of the presence of chromium oxide.

The Court also examined the commercial logic behind the trademark filings and the chronology of events. It emphasized that Ceramtec knew that its patent monopoly was expiring and filed its applications for registration a few days after the expiration of its patent, while it had not done so before. The Court indicated that, although the same product may be protected by several industrial property rights, the succession of those rights must not be used to protect the same characteristic of the product, in this case, its technical characteristic, in order to unduly extend the monopoly initially conferred by the patent.

The Court concluded that Ceramtec had filed its trademarks in bad faith, which were thus invalid, and awarded Coorsteck damages because of Ceramtec's unfair conduct. Ceramtec, which had acted with the intention of prolonging the protection of the material covered by the patent in order to prevent its competitors from marketing products of the same nature and strength and to protect access to its market. Ceramtec therefore intended to obtain an exclusive right for purposes other than those falling within the function of a trademark, namely the indication of origin.

With respect to free riding claims, the Court considered that, since the color pink is not perceived as an arbitrary element, it cannot be considered providing separate economic value for Ceramtec and rejected the claims on this basis.

REVOCATION PROCEEDINGS - PROOF OF GENUINE USE OF THE TRADEMARK - BUNDLE OF ELEMENTS - PROBATIVE VALUE

European General Court, July 7, 2021, Case: T205/20, Ms X v. Minerva GmbH and EUIPO

The European General Court ruled that a bundle of evidence may establish the facts to be proven, even where none of these elements taken in isolation, would establish the such facts. However, in this case, the Court found that the evidence assessed as a whole was insufficient to establish genuine use of the trademark.

Minerva GmbH filed an application with the EUIPO for revocation of the European Union word trademark No. 8836661 "*Icosmetics*", owned by Ms. X for various goods and services, including "*cosmetics, skin care products, in particular skin creams, lotions for cosmetic use*" in Class 3.

The Cancellation Division, and then the Board of Appeal of the EUIPO, found that the evidence submitted by Ms. X did not make it possible to establish genuine use of the trademark "*Icosmetics"*, based on Regulation No. 207/2009 and Regulation No. 2868/95 as applied to the facts, a decision which was confirmed by the Court.

After recalling that the requirement of genuine use is not intended to evaluate commercial success, nor to control the economic strategy of an undertaking or to restrict the protection of trademarks to those that are subject of significant commercial exploitation, the Court clarified the elements of proof that must be taken into consideration. It held that the burden of proof of genuine use lies with the holder of the contested trademark with respect to all of the criteria

to be taken into consideration, namely the duration, place, nature and importance of the use.

Regarding the duration of use, the Court pointed out that elements subsequent to and prior to the relevant period (five years preceding the filing of the application for revocation) may be taken into account in assessing the genuine nature of the usage of a trademark. However, the Court found that considering such elements would necessarily require the submission of documents demonstrating the usage of the trademark for such period. In the present case, the Court found that the EUIPO correctly assessed the probative value of the documents submitted to it.

Regarding the significance of the usage, the Court pointed out that the revenue achieved, and the quantity of goods sold under the trademark cannot be assessed in absolute terms but must be assessed in relation to other relevant factors, such as the volume of commercial activity, the production or marketing capacities or the degree of diversification of the undertaking using the mark, and the characteristics of the goods on the market. The Court concluded that even minimal use may be sufficient to be regarded as genuine, if it is regarded as justified, in the economic sector concerned, for the purpose of maintaining or creating market shares. The Court therefore refused to set a minimum quantitative threshold. However, in the present case, the Court affirmed the EUIPO's analysis, which had found that the evidence submitted by the holder of the trademark '*Icosmetics*' did not prove any concrete facts as to the extent of the usage. Accordingly, the Court concluded that the holder of the trademark had not demonstrated the use of the contested trademark during the relevant period.

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