JUDGMENT

Civil cassation sec. I - 05/07/2024, no. 18372

Header

ITALIAN REPUBLIC
IN THE NAME OF THE ITALIAN PEOPLE THE SUPREME COURT OF CASSATION
SECTION ONE CIVIL

Composed of Messrs:

Dr. SCOTTI Umberto Luigi Cesare Giuseppe — President Dr.
MARULLI Marco — Adviser
Dr. IOFRIDA Giulia- Consigliere - Rel.
Dr. TERRUSI Francesco - Councillor
Dr. FALABELLA Massimo — Adviser

delivered the following opinion

JUDGMENT

on the appeal registered under No. 2224/2022 R.G.

proposed by:

SICOR Srl, TEVA PHARMACEUTICAL INDUSTRIES LIMITED, electively domiciled in ROME Lungotevere Michelangelo 9, at the office of lawyer GALLITTO NICCOLÒ ANTONINO (omissis) who represents and defends them jointly to the lawyers BIAMONTI LUIGI (omissis), BERGIA STEFANIA (omissis), SIRONI GIULIO ENRICO (omissis);
- recurring -

v.

Bo.In. PHARMA GMBH AND CO. KG, electively domiciled in ROME VIA TOSCANA 1, at the office of the lawyer CERULLI IRELLI GIUSEPPE represents and defends it together with lawyers CAPELLI DONATELLA ANNA (omissis), CUONZO GABRIELE (omissis), TREVISAN LUCA (omissis);
- counterclaimant -

against JUDGMENT OF COURT OF APPEAL MILAN No. 1785/2021 filed on 08/06/2021.

Hearing the report delivered at the public hearing on 12/06/2024 by Councillor GIULIA IOFRIDA

The defence lawyers for the applicants, Mr Bergia and Mr Sironi, and for the opposing party, Mr Trevisan and Mr Cerulli Irelli, gave oral arguments.

the conclusions of their respective acts.
Having heard the Attorney General, Dr Andrea Postiglione, who concluded for the dismissal of the appeal.

FACTS OF CAUSATION

The Court of Appeal of Milan, by judgment No. 1785/2021, published on 8/6/2021, confirmed judgment No. 8273/2018 of 24/7/2018 of the Court of Milan, by which - in proceedings instituted, in May 2014, at the outcome of provisional description proceedings (granted), by Bo.In. Pharma GmbH E Co. KG, owner of the patent (omissis), filed on 12.9.1990 and validated in Italy, on 27.6.1994, claiming a class of compounds comprising 'tiotropium bromide, an anticholinergic bronchodilator active ingredient, to be administered by inhalation in broncho-constructive pathology', used in the drug Spiriva, against Teva Pharmaceutical Industries Spa and Sicor Società Italiana Corticosteroidi Srl, in order to establish the infringement of the exclusive rights arising from EP '716/CCP '849 put in place by the defendants - the counterclaim brought by the defendants, seeking a declaration of invalidity of CCP '849, owned by Bo.In. Pharma GmbH E Co. KG., on the basis of the conclusions of the expert witness Dr. Spadaro.

In the same proceedings, it was ascertained and declared, in upholding the main claims of the plaintiff company Bo.In., that the production, marketing, importation, exportation, distribution and advertising by the defendants of tiotropium bromide in any form, including the anhydrous and monohydrate forms described in the proceedings (on the basis of the purely pharmacological expert's report prepared by Prof. Ca., in relation to Sicor's production and sale of quantities of tiotropium bromide compatible with the production of industrial-scale batches of a generic version of the product SPIRIV), constituted an infringement of the Italian portion of patent EP 716 (expired on 12 September 2010) and of CCP 849 (expired in September 2016), as well as an act of unfair competition, and the case was remitted to the court by virtue of a separate order, in order to continue the preliminary investigation phase with regard to the claim for damages.

In particular, the matter at issue, which is still of interest in this court of law, concerned the interpretation of Article 68(1)(b) of the Code of Criminal Procedure, the result of the implementation in Italy of Directive 2001/83/EC (Article 10(6)), later amended by Directive 2004/27/EC, which states: "the exclusive right conferred by the patent does not extend, regardless of the subject-matter of the invention: ... b) to studies and experiments aimed at obtaining, even in foreign countries, a marketing authorisation for a pharmaceutical product and the consequent practical steps, including the preparation and use of the pharmacologically active raw materials strictly necessary for that purpose") (the so-called "Bolar clause", a principle of US origin, deriving from the dispute between Roche and Bolar concerning the

patent infringement relating to the active ingredient Flurazepam, which was available to the former and resulted in the regulatory intervention to liberalise the trials necessary to obtain the marketing authorisation).

The Court pointed out, on the one hand, that the underlying rationale of this clause is to facilitate the timely entry of generic drugs on the market in order not to extend, in fact, the duration of the patent, allowing generic manufacturers to begin the administrative and testing activities preparatory to obtaining a marketing authorisation, even while the reference patent is in force, thus introducing limits to the right of exclusivity, and, on the other hand, that this is a rule of strict interpretation which, although it does not allow, under Article 14 of the law, the analogical interpretation, it does however allow the broad interpretation, always with a view to balancing, on the one hand, patent protection and, on the other, the practical needs of the market, and always with a view to the practical needs of the market, on the one hand, and the need to protect the patent, on the other. On the other hand, that this is a strict interpretation which, although it does not allow, under Article 14 of the law, the analogical interpretation, it does, however, allow the extensive interpretation, always with a view to balancing, on the one hand, patent protection and, on the other, the practical-experimental needs, prodromal to the commercial launch of a generic drug.

It was therefore held by the judges at first instance, in the face of Bo.In.'s argument according to which the Bolar exception could apply only to those persons who, internally, carry out activities of preparation and use of the active ingredient in order to prepare the documentation relating to their own application for authorisation to market the medicine (AIC), that (a) the Bolar clause cannot apply to mere producers/resellers of active ingredient, i.e. to those who carry out experimentation and production activities not aimed at obtaining a marketing authorisation, but aimed at obtaining the active ingredient covered by the patent and offering it for sale to others; (b) the exception is however also applicable to the activity of third parties who produce the active ingredient of the patented drug, for registration purposes not of their own but of third parties and at the request of such generic manufacturers, who are not equipped to produce on their own, but intend to enter the market, upon expiry of the exclusivity of the patent title, inasmuch as, in such cases, "the activity of the third party is closely linked to that of the generic manufacturer who intends to obtain the marketing authorisation, and the profit derived therefrom constitutes remuneration for the service rendered, by making available his skills, experience and technological tools", and in fact the provision of Art. 68, paragraph I, lett. a) c.p.c. admits the experimental activity insofar as it is commissioned to third parties in exchange for a consideration; c) "the Bolar exception, although it could also be applied to the activity of persons who produce the active ingredient for registration purposes that are not their own but those of others, presupposed, in any event, that such production and marketing activity was carried out at the request of the generic manufacturers and not autonomously and independently".

On the contrary, Teva and Sicor had acted as mere producers of the active ingredient, having offered for sale - an activity already in itself excluded from the exemption - and sold the active ingredient in the absence of the exemption, by carrying out promotional activities and offering for sale the active ingredient tiotropium bromide on the website, in itself incompatible with the application of the Bolar exemption, since the third producer would have had to act at the request of the

generic and did not offer to search for potential customers; furthermore, the companies themselves had not taken any precautionary measures to prevent the active ingredient offered and sold from being used for purposes unrelated to the 'Bolar clause'.

The Court of Appeal, ruling on the sole ground of appeal brought by Sicor and Teva against the partial judgment at first instance, stated that, as correctly held by the court of first instance, the 'Bolar clause' was a provision of an exceptional nature, intended to allow 'the performance of all those activities, experimental and administrative, having a preparatory function with respect to the marketing authorisation of generic products, that is to say, products containing the same active ingredient as medicinal products for which the patent exclusivity on the active ingredient has expired", conferring "greater rapidity in the entry of generic medicines onto the market, since the generic manufacturer is not obliged to complete all the clinical studies necessary to demonstrate the efficacy and safety of the product, relying on the studies already carried out in relation to the reference drug, the so-called originator".d. originator", considered correct the interpretation offered by the Court, according to which the Bolar clause cannot apply to mere producers/resellers of active ingredients, in a view of a compromise between the freedom of economic initiative in a particularly significant sector for the world community, that of pharmaceuticals, and the necessary protection of the owner of the patent. Consequently, generic traders lacking the necessary technological equipment and skills may turn to third party producers of the active ingredient to request a production and delivery activity, to be considered legitimate insofar as it is functional to obtaining a marketing authorisation, but "the activity of the third producer, since it cannot be released from a specific request of the generic trader, cannot include a true and proper marketing activity... in contrast with the experimental and registration purposes typical of the exception permitted by the legislative provision".

In the present case: (a) Sicor and Teva, not specifically challenging that interpretation of the provision, admitted in their own acts that they had commenced the activities of production and advertising of tiotropium, prior to and independently of a specific request and mandate by a generic company, in contrast precisely with the even broad interpretation admitted by the trial judge; (b) the mere inclusion of the product on the website constitutes an expression of the known marketing activity, functional to capture the attention of possible generic customers c) with regard to the warnings addressed to genericists, concerning the fact that they can only sell for Bolar purposes, on the website (omissis), the disclaimer was inserted in 2014, after the description of July 2013, while it did not appear in the 2012 product catalogue and was eliminated in the 2015 catalogue, as admitted by the defendants themselves, albeit by mistake, and in any event referred in general to all products, not specifically to the tiotropium principle (d) the rectification concerning the authorisation requested from AIFA, for the production of tiotropium bromide for the purposes of clinical trials only, even if obtained by mere error for commercial purposes, could not legitimise the advertising and marketing carried out via the internet; (e)

those findings made it unnecessary to examine whether the quantities of tiotropium bromide were compatible with the purpose of marketing in order to exclude it, so as to find that the Bolar exemption was satisfied, and even more unnecessary was the examination of the question of the quantity of active ingredient sold in Turkey to the Turkish company Neutec inasmuch as the constituent elements of the Bolar exemption were not integrated 'once it is accepted that Sicor and Teva produced the tiotropium bromide on their own initiative, offering it for sale indiscriminately, in the absence of stringent and clear negotiating clauses and in the absence of punctual negotiating regulations capable of ensuring exclusive registration use since 2012'.

In conclusion, the Court of Appeal, confirming the first instance decision and rejecting the appeal, stated that "the producer of the active ingredient, in order to benefit from the exception of the Bolar clause, must demonstrate that it has acted on the input of a generic subject and that it has adequately regulated and supervised by negotiation (for example, with the provision of a penalty) the fact that the generic manufacturer will only use the active ingredient for Bolar purposes" and that "in the absence of these conditions, the quantities of the active ingredient realised and sold by the manufacturer appear totally irrelevant, and this all the more so in view of the extreme variability of the quantities necessary for the experimental/registration phase".

Sicor Srl and Teva Pharmaceutical Industries Limited bring an appeal on a single ground of appeal, notified on 10/1/2022, against that judgment against Bo.In. Pharma GmbH E Co. KG (which is responding by way of a counter-appeal served on 21/2/2022).

Both parties filed pleadings.

By interlocutory order No. 21679/2023, the case was adjourned to the chamber meeting of 23/5/2023 for hearing in open court.

The PG filed a brief, concluding that the appeal should be dismissed.

The appellants and the opposing party filed further pleadings.

At the public hearing on 12 June 2024, the parties' counsel was heard, who orally presented their respective submissions, and the public prosecutor, who concluded for the dismissal of the appeal.

REASONS FOR THE DECISION

1. The appellants complain, in a single ground of appeal, of the breach or false application of Article 68(1)(b) of the IPC in relation to Article 360(1)(3) of the Code of Civil Procedure, criticising the judgment of the Court of Appeal of Milan for holding that the exception under Article 68(1)(b),
c.p.i. applies to third party producers of active ingredients only on condition that (a) the

production of the active ingredient takes place at the specific request of the generic manufacturer concerned, and (b) the manufacturer engages in a course of conduct that is neither expressly mentioned nor implicitly required by the rule in question.

The Sicor and Teva companies, while agreeing with the extension by way of interpretation of the list of persons who, in view of the ratio of Article 68 under examination, can benefit from the Bolar exemption (including third parties who produce the patented active ingredient, in order to supply it to generic manufacturers who are not equipped to produce it on their own, but intend to enter the market upon the expiry of the exclusivity of the patent title, so as to allow such generic manufacturers to avail themselves of the activity of mere external producers in order to have timely access to the procedures for the granting of marketing authorisations), they contest the inadmissible 'creative' interpretation made by the judges of merit, through the addition of a series of stringent requirements and additional conditions that find no justification either in the text of the rule or in the ratio of the same as identified by the judgments, namely "a) the commencement of production (and, even before that, of the experimental activities necessary to prepare an adequate production process) only upon the request of the third generic manufacturer and b) the stipulation of "adequate" contracts committing the third generic manufacturer to compliance with the Bolar exemption".

For the applicants, this is an unfairly additive interpretation, as well as being illogical and impossible to apply in practice.

The judgment under appeal, the appellants submit, in prohibiting the manufacturer of active ingredients from informing third parties of its ability (in terms of skills, machinery, personnel, ...) to produce a given active ingredient 'before it has received a request for supply', renders the Bolar exemption inapplicable in practice, on the basis of the following objections: (a) 'how can the manufacturer be approached by interested generic third parties if the latter cannot be made aware of its availability to produce?"; b) "third-party generic manufacturers interested in commissioning the production of an active ingredient would have to sound out the availability of an indefinite number of possible manufacturers before finding one available"; c) "alternatively, the generic manufacturer would be forced to turn to manufacturers of active ingredients who would cite the active ingredient of interest among those for the production of which they have the necessary facilities, and located in countries not covered by the patent or SPC, thus rendering the subjective extension of the rule completely futile".

On the contrary, the manufacturer may well begin, well in advance of the receipt of supply requests (also in relation to the long lead times, at least three years, required for the 'fine-tuning of the production process - necessary for the supply of an active ingredient characterised by a sufficient degree of purity', to which must be added the time - approximately one year - imposed by the bureaucratic process required to obtain an authorisation to produce the active ingredient for experimental and clinical use, necessary to be able to start production of the active ingredient precisely at the experimental end), to

produce 'under

Bolar' the active ingredient even in the absence of applications by generic manufacturers, the manufacturer itself having made it clear that the (eventual) supply of that active ingredient would only take place under the same Bolar conditions and would be for the purpose of the generic manufacturers' AIC application activities.

Otherwise, the interpretation of the judges on the merits - in essence, abrogating - would have precisely the effect of restoring "that unjustified discriminatory treatment - criticised, inter alia, also by the first instance judgment12 and in any event contrary to Art. 10.6 of Directive 2001/83/EC - between generic traders with adequate production facilities (i.e. the economically stronger generic traders, who could start at any time the activities of production of the active ingredient and therefore the activities necessary to obtain a marketing authorisation) and generic traders without such facilities (i.e. generic traders with fewer resources, who would have to suffer this hiatus of almost 10 years!) that the meritorious broad interpretation of the previous rulings had averted".

Moreover, the Court of Appeal, in breach of Article 115 of the Code of Civil Procedure, also misinterpreted the statements of Sicor and Teva, which had always 'declared that the experimental activities initiated by Sicor were intended to enable one or more companies of the Teva Group (therefore, technically, generic third parties) to obtain a marketing authorisation' and that the activities in question 'therefore commenced in any event after receipt of an application from a third company other than Sicor'.

The objection regarding the additive interpretation made by the judges on the merits is also directed with reference to the second condition, identified under (b), i.e. the need for the prior stipulation of "appropriate contracts committing the third generic supplier to compliance with the Bolar exemption".

If the sole condition of lawfulness is the experimental and registration purpose (to be assessed ex ante) (and therefore the fact that the manufacturer intends to produce and supply the active ingredient to allow third-party generic manufacturers to obtain the necessary marketing authorisations), the final (ex post) decision of the third-party generic manufacturer as to the use of the active ingredient in question cannot be of any importance. Moreover, a private negotiation agreement (even if backed by a penalty) could in no way guarantee that the generic third party would refrain from committing acts of counterfeiting, and in any event the active ingredient manufacturer could not be blamed for this, especially when - as in the present case - it had taken steps, by means of disclaimers letters signed by customers, warnings on products and delivery notes, to warn the third party generic manufacturer - at the time of supply but also before, i.e. already at the time of the information activity on the availability of the active ingredient tiotropium bromide - of the only purpose for which the use of the active ingredient was permitted.

1.2. The applicants ask this Court to submit the following questions of law to the CJEU:

"Is Article 10(6) of Directive 2001/83/EC to be interpreted as meaning that the exclusion of patent protection (possibly extended by means of a supplementary protection certificate) in respect of acts whereby a third party offers or supplies to a generic company a patent-protected active ingredient which the generic company has intended to use in order to carry out studies and trials with a view to obtaining a marketing authorisation for medicinal products within the meaning of Article 10(6) of Directive 2001/83/EC requires

a) that the third party waits to receive from the generic company a specific request for supply before commencing any preparatory activity, including, for example, the activity of informing it of the third party's willingness to supply that active ingredient, the activity of preparing internally a manufacturing process for the active ingredient in question, the activity of preparing the Drug Master File relating to that active ingredient, the activity of manufacturing the active ingredient for the purpose of its supply for registration purposes;

b) that the third party signs with each generic company precise contractual agreements by which: i) the third party prohibits the generic company from any non-registration use of the active ingredient, assisting this prohibition with private coercive instruments (e.g. penalty clause, indemnity clause,...); and ii) the generic company undertakes to use the active ingredient exclusively for registration purposes'.

1.3. The counter-appellant first of all objects to the inadmissibility of the plea, pointing out that it is not possible to re-examine the interpretation of Article 68(1)(b) of the Code of Criminal Procedure in a sense that may be more favourable to Sicor/Teva, that interpretation having become final, as the Court of Appeal found in a ruling also not challenged by the appellants.

The exception is unfounded.

In fact, the Court of Appeal acknowledged that Sicor and Teva "expressly agreed with the interpretation of the Bolar clause as set out by the trial judge, therefore with an adequate appreciation of the teleological perspective underlying Article 68(1)(b) of the Code of Civil Procedure."but disagreed, instead, "with the factual assessment of the violation of the exemption clause", except then clarifying that the requirements that, in the Court's opinion, the Bolar clause, in order to satisfy the declared purpose of registration, had to meet had been contested, namely that (a) the purpose had to be declared in advance and known not only at the time of the transfer, but also with respect to the production, offer for sale and marketing of the active ingredient and that (b) the purpose had to be indicated by the transferor as a limitation of use.

Thus, the interpretation of the so-called Bolar exception as offered by the CFI had been appealed on appeal and cannot be said to be domestic res judicata precluding consideration of the plea.

Nor can it be held that the Court of Appeal, having in any event considered the objections raised by Sicor/Teva "and considered (by Sicor/Teva, ed.) not adequately assessed by the Court of First Instance, in the light of which the production of the active ingredient should be deemed to be covered and endorsed by the Bolar clause", the Court of Appeal ascertained, with an independent ratio decidendi (with respect to the interpretation of the Bolar exception adopted), that Sicor/Teva had not produced and marketed the "tiotropium bromide" at the request of generic manufacturers but on their own initiative, also verifying, however, the concrete methods of advertising and offering for sale of the "tiotropium bromide" adopted by Sicor/Teva, so as to exclude, however, that even an interpretation of the clause, in line with that asserted by the opposing party (according to which the activity of the third party producer of active ingredients could be considered exempted even when it acts on its own initiative, and not upon the genericist's input), could have led to a successful outcome of the opposing appeal.

Indeed, those findings, far from supporting an independent rationale, are part of the interpretation adopted of the Bolar exception and of the constituent elements, which, in the present case, did not appear to be fulfilled, 'once it is accepted that Sicor and Teva produced the tiotropium bromide on their own initiative, offering it for sale indiscriminately, in the absence of stringent and clear negotiating clauses and in the absence of as many precise negotiating regulations capable of ensuring exclusively registered use since 2012'.

1.4. The opposing party then pleads that the plea is inadmissible for lack of interest.

This is because the appellants' argument, according to which it is wholly irrelevant that the conduct of the manufacturer of the active ingredient is preceded by a specific request on the part of the generic manufacturer, 'since the manufacturer itself is quite clear that the (eventual) supply of that active ingredient will take place only on the same Bolar conditions and will be aimed at the performance of the activities of application for marketing authorisations by those generic manufacturers', lacks the necessary factual prerequisites, since no evidence has come to light in the judgment on the merits that the offer for sale and supply took place 'on Bolar's terms' and was aimed at the performance of the AIC application activities by those generic traders.

The exception is likewise not worthy of acceptance.

Indeed, the assumption of the applicants is that they can take advantage of the Bolar exemption, as third party producers of the patented active ingredient, to supply it to generic manufacturers who are not equipped to produce it themselves, but intend to enter the market upon expiry of the exclusivity of the patent title in order to obtain the necessary MAs, and that they

may commence the experimental activities necessary to set up an adequate production process, regardless of a prior request from the generic third party and the stipulation of appropriate contracts committing the generic third party to compliance with the Bolar exemption or specific arrangements on the part of said third party manufacturers (notices, disclaimers, etc.).

2. That said, the sole ground of appeal is, however, unfounded.

2.1. Article 68 Legislative Decree No. 30/2005, "Limitations of the patent right", in its current wording, following the amendments introduced by Legislative Decree No. 18/2019 (which, in adaptation of the national legislation to Reg. 1257/2012 and the Agreement on a Unified Patent Court, ratified and made enforceable pursuant to Law No. 214 of 3 November 2016, amended the provision, introducing letters a-bis, c-bis and c-ter) and Law No. 214/2023 (which amended letter c), reads as follows:

"The exclusive right conferred by the patent right does not extend, whatever the subject matter of the invention:

a) acts done privately and for non-commercial purposes; a-bis) acts done for experimental purposes relating to the subject matter of the patented invention, or to the use of biological material for cultivation purposes, or to the discovery and development of other plant varieties;

b) studies and experiments aimed at obtaining, also in foreign countries, a marketing authorisation for a drug and the consequent practical steps including the preparation and use of the pharmacologically active raw materials strictly necessary for this purpose;

c) the extemporaneous, unit-based preparation of medicines in pharmacies on medical prescription, and the medicines thus prepared.

(c-bis) the use of the patented invention on board ships of other countries of the International Union for the Protection of Industrial Property (Paris Union)..."

The text of the first paragraph of Article 68 of the IPC prior to the amendments introduced by Legislative Decree 131/2010 read as follows:

"The exclusive right conferred by the patent right does not extend, whatever the subject matter of the invention:

a) to acts performed privately and for non-commercial purposes, or on an experimental basis;

b) studies and trials aimed at obtaining, also in foreign countries, a marketing authorisation for a drug and the consequent

practical tasks including the preparation and use of pharmacologically active raw materials strictly necessary for this purpose;

c) the extemporaneous, unitary preparation of medicines in pharmacies on medical prescription, and medicines prepared in this way, provided that no industrially manufactured active ingredients are used'.

The version prior to the 2010 amendments provided, in subparagraph (a) of the first paragraph of Article 68, that the exclusive right conferred by the patent right did not extend, regardless of the subject matter of the invention, (a) "to acts performed privately and for non-commercial purposes, or on an experimental basis, even if aimed at obtaining, also in foreign countries, a marketing authorisation for a pharmaceutical product and the consequent practical steps including the preparation and use of the pharmacologically active raw materials strictly necessary for that purpose".

The 2010 Reform therefore proceeded to distinguish between the two hypotheses of exclusion, thus keeping separate, on the one hand, experimental use (to be understood as being limited only to the hypotheses of experiments conducted on the invention with a view to its passing, and not its implementation), and, on the other hand, the activities preparatory to obtaining the Medicinal Products' MA.

In the present case, point (b) of the first paragraph of Article 68 of the IPC, which remained unchanged after the 2010 and 2019 amendments, is relevant.

2.2. It should be recalled that the Inventions Law under Royal Decree no. 1127/1939, as amended by Presidential Decree no. 338/1979, already provided in the third paragraph of Article 1: "The exclusive right conferred by the patent right does not extend, whatever the subject matter of the invention: a) to acts performed privately and for non-commercial purposes, or experimentally, b) to the extemporaneous preparation, and per unit, of medicines in pharmacies on medical prescription, and to medicines prepared in this way".

It should also be pointed out that, in the field of pharmaceuticals, in order to bridge the time lapse between the date of filing of the patent application and the date of authorisation to market, a time necessary for the due complex verifications but which delays the exploitation of the invention, Law No. 349 of 19 October 1991 (which led to the addition, in the body of RD 1127/1939, of art. 4-bis) introduced, for the first time in Italy, the "complementary certificate of protection", in short CCP, in order to meet the requests of the pharmaceutical industry to extend the duration of patent protection (normally equal to twenty years from the filing of the patent application), in the field of medicinal specialties, so as to be able to recover the time lost in the commercial exploitation of the invention, until obtaining, following appropriate chemical experimentation, by the health administration, the indispensable Authorisation

placing on the market, AIC for short (by means of registration by the Ministry of the Interior pursuant to art. 162 T.U. Leggi sanitarien. 1265/1934, as replaced by art. 4 of Law 422/1941), also requiring considerable scientific, technical and financial efforts.

In fact, Article 4-bis of the Inventions Act provided for extended protection for a duration always and invariably 'equal to the period between the date of filing of the patent application and the date of the decree granting the first marketing authorisation of the medicine', up to a maximum of eighteen years.

2.3. At European level, on 18 June 1992, in order to minimise the differences created by the different national regulations of the member States and to protect the European pharmaceutical industry (above all in the face of the protection introduced by the United States and Japanese regulations), ensuring a common discipline for all the European States, EEC Regulation No. 1768/1992 was issued, which came into force at the same time in all the countries of the Community on 2 January 1993, with the consequent absorption of the previous Italian discipline. According to Article 1 of Regulation No. 1768/92, holders of a patent for an invention having as its object "a medicament, a composition of active ingredients of a medicament, a use of a product (active ingredient or composition of active ingredients of a medicament) as a medicament, a process for the manufacture of a medicament" could obtain a Supplemental Protection Certificate (SPC), provided that it had obtained registration for the purpose of marketing the medicament itself.

The Community legislature therefore introduced 'SPC' rules (acronym for Supplementary Protection Certificate, also called in Italy 'CPC', which stands for Certificato Protettivo Complementare) in respect of medicinal specialities (and subsequently also plant protection products) in order to "grant to the inventor of the medicine, in addition to the patent a 'complementary' patent aimed at extending the duration of the exercise of the exclusive exploitation rights of the invention in order to compensate, at least in part, for the years elapsed between the grant of the patent title and the placing on the market of the medicine, which requires the performance of controls by the Public Administration ".

With the entry into force of E.C.E. Regulation No. 1768/92, on 2 January 1993, Article 4-bis of the Inventions Act was implicitly repealed and replaced precisely by the provisions contained in that Regulation. The Regulation did, however, expressly leave intact the supplementary certificates granted under the national laws whose place it had taken, providing in Article 20 that "This Regulation shall not apply either to certificates granted in accordance with the national law of a Member State before the date of entry into force of this Regulation or to applications for certificates filed in accordance with that law before the date of publication of this Regulation in the Official Journal of the European Communities".

In order to resolve certain situations of uncertainty, Community Regulation No. 1610 of 8/8/1996 was subsequently issued, which established the Supplementary Protection Certificate also for plant protection products. In fact, recital 13 of the aforementioned Regulation states that "the certificate confers the same rights as the basic patent".

Regulation No. 1610 was later replaced by Reg. No. 469/2009/EC of 6 May 2009.

2.4. With Directive No. 2004/27/E.C., amending Directive No. 2001/83/E.C., known as the European Medicines Code, the Community legislator then regulated the procedures for granting MAs or MAs.

In Article 10.6 of the Directive it was provided that '6. The performance of the studies and experiments necessary for the application of paragraphs 1, 2, 3 and 4 and the consequent practical requirements shall not be regarded as contrary to patent law or to supplementary protection certificates for medicinal products".

In a pro-competitive rationale of the provision granting patent right holders in the pharmaceutical sector prolonged protection in order to limit its scope to what is necessary to meet the compensation requirement underlying such prolongation, without imposing further limitations on independent producers, correctives have been introduced at European level: this need - and thus the rationale for the prolongation of protection obtained through the granting of 'SPCs' is closely linked to the need to compensate for the delay in the entry into European markets of the (first) pharmaceutical product which is made in implementation of what constitutes the 'heart' of the patent, a delay due precisely to the regulatory procedures which, in the pharmaceutical sector, make this entry in Europe as a rule more distant than in other economic sectors.

In essence, the supplementary protection certificate extends patent protection beyond the natural expiry of the patent, for a duration equal to the period between the filing date of the basic patent application and the date of the first marketing authorisation ('MA'). The time extension relates to the active ingredient claimed by the patent and present in the authorised drug.

Generic medicinal product, within the meaning of the 2004 Directive, means a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, as well as a bioequivalence with the reference medicinal product demonstrated by appropriate bioavailability studies.

2.5. The Agreement on the Unified Patent Court, 2013/C 175/01, in Article 27, first paragraph, 'Limits of the effects of a patent', for what is of interest here, states that: "The rights conferred by a patent shall not extend:

a) to acts performed in private and for non-commercial purposes;

b) acts performed for experimental purposes relating to the subject matter of the patented invention;...".

On 1 July 2019, the discipline of the so-called "SPC Manufacturing Waiver" came into force: a new EU Regulation that amended the discipline of complementary protection certificates, allowing in the territory of the European Union the production of active ingredients still covered by a "SPC" for export to countries where patent or complementary protection does not exist or has already expired and (more limitedly) for the storage of them with a view to placing them on the market immediately after the expiry of the certificate. This is in order to offset the "competitive disadvantage" of European manufacturers of generic drugs vis-à-vis manufacturers operating in third countries where there is less or no complementary protection offered.

2.6. Article 68(1)(b) of the C.P.I. (the result of the transposition of Article 10.6 of Directive 2001/83/EC, later amended by Directive 2004/27/EC) therefore provides for the lawfulness of experimentation activities of a drug covered by another person's patent, aimed at obtaining an administrative authorisation to market the drug, which is intended to operate after the expiry of another person's patent.

All this with a view to marketing the generic drug immediately after patent expiry.

It is only to be recalled that, already in 2002, our legislator had sought (with Decree-Law No. 63/2002, converted into Law 112/2002) to introduce, alongside a progressive reduction in the duration of the "CCPs" still in force, also the express provision of the faculty for "companies intending to produce pharmaceutical specialities outside patent cover" to "initiate the registration procedure for the product containing the active ingredient one year in advance of the expiry of the complementary patent cover of the active ingredient".

It must be pointed out that Legislative Decree 219/2006, implementing Directive 2004/27/EC, also provides in Article 10 that: "The performance of the studies and experiments necessary for the purposes of the application of paragraphs 1, 2, 3, 4, 5, 6, and 7 shall not affect the protection of industrial and commercial property".

Both Legislative Decree No. 219/2006 and the Directive, with regard to the drugs, which are the subject of the marketing authorisation application, refer only to the studies and trials necessary for the application of the paragraphs regulating one of the 'special' authorisation regimes concerning generic drugs, biosimilars, and so-called 'hybrid' drugs, not also to 'innovative' drugs.

2.7. The name 'Bolar Clause' derives from a well-known court case that had pitted a generic company, Bolar Pharmaceutical Co. against Roche in the United States, with ups and downs.

In 1983, Roche had sued Bolar in the District Court for the Eastern District of New York for infringement of its patent on 'Flurazepam', because Bolar had procured a small quantity of the product from a foreign manufacturer a few months before the patent expired in order to conduct the studies and experiments necessary to submit an application to the US Food and Drug Administration (FDA) for marketing authorisation of the corresponding generic drug (Paper New Drug Application). In the first instance, Bolar prevailed in view of the recognised experimental nature of its activity and its marginal nature. On appeal, the Court of Appeals for the Federal Circuit overturned the first decision, holding that the use of a patented drug for the sole purpose of obtaining authorisation to market the corresponding generic drug did not fall within the experimental use exception and therefore constituted infringement, since it could not be carried out before the patent expired. The US legislature had therefore intervened with the law known as the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act 1984), which made an amendment to the Federal Food, Drug and Cosmetic Act, aimed precisely at rendering legitimate the experimental activities aimed at obtaining market authorisation (MA) of a generic drug even when they involved the implementation of a patent still in force.

The name 'Bolar Clause' has therefore since been used to designate the rules establishing that patent exclusivity cannot be opposed to activities, not authorised by the patent holder, if they are directed to obtaining marketing authorisations for a generic drug interfering with patent protection, and first and foremost to the production of samples of the drug and subjecting them to bioequivalence experiments, i.e. experiments aimed at proving that the generic drug possesses the same therapeutic efficacy and degree of safety as the 'original' drug.

Directive 2004/27/EC, which amended Directive 2001/83/EC, the so-called Community code for medicinal products, introduced the Bolar exemption in Europe.

The patent holder may therefore not oppose the performance of activities preparatory to obtaining a marketing authorisation ('MA') for a drug for which the patent or supplementary protection certificate has not yet expired.

The text of the national standard, after amendment by Legislative Decree 131/2010, corresponding to Directive 2001/83/EC as amended by Directive 2004/27/EC, having separated point (b) (referring to 'studies and experiments aimed at obtaining, also in

foreign countries, a marketing authorisation for a medicinal product and the consequent practicalities, including the preparation and use of pharmacologically active raw materials strictly necessary for that purpose'), from the hypothesis of the letter (a) (concerning acts performed 'on an experimental basis'), it is in the sense that, for the purpose of the exception at issue, it is not the purely experimental nature, but the purpose of obtaining the 'MA' that makes the activities covered lawful even when the drug is still covered by a patent or supplementary protection certificate.

2.8. It is not in dispute that the underlying rationale of the Bolar clause is to facilitate the timely entry of generic drugs onto the market in order not to 'de facto' prolong the duration of the patent protection, since this exemption allows all the administrative and testing activities preparatory to obtaining a 'MA' to be carried out even while the reference patent is in force.

The Community legislator (and the Italian legislator as a consequence) had, in fact, to achieve a balancing act between opposing interests belonging to holders of subjective rights: that of the owner of industrial property, who has an exclusive right, and that of the companies which, upon the expiry of the patent, have the right to the full and immediate re-expansion of the freedom of economic initiative by intending to compete on the market with the owner of the same.

Article 68 of the IPC, or the so-called Bolar clause, introduces limits to the right of exclusivity that patent ownership confers, justified by distinct requirements deserving of overriding protection; limits that constitute, therefore, exceptions to the rule of the fullness of the patent right, which, in the absence of the provisions of the law in question, would require the conduct provided for therein to be qualified as infringement.

The pharmaceutical patent right is thus restricted, as it cannot be extended to the activities necessary to obtain a marketing authorisation ('MA') for a drug, which would fall within the scope of the patent itself.

The controversial issue in the interpretation of the rule, at a national and European level, in the present case, is that of the objective or subjective extension of the Bolar exception: in fact, it is a question of establishing whether the production of the active ingredient and the subsequent experiments must be considered lawful, because they fall within the exception, only if the subject carrying them out is the same as the one applying for the marketing authorisation or, instead, whether the exception also applies to the same activities carried out, however, by a third party supplier, not applying for the marketing authorisation.

The interpretation of the European Directive was the subject of a dispute between 2011 and 2013 involving the Polish company Polpharma SA, owner of patent EP 0 801 067 B1, and the Japanese pharmaceutical company Astellas Pharma Inc, in Germany and Poland.

concerning the production of the active ingredient 'solifenacin succinate', which fell within the scope of Astellas' patent protection. Polpharma had advertised and sold the active ingredient to several generic manufacturers, including at least one in Germany. Astellas had then sued Polpharma for patent infringement, both in Poland and in Germany, and Polpharma, in its defence, had argued non-infringement, on the basis that its acts fell within the application of the so-called Bolar exception and that the purchasers of the active ingredient would then actually use it only for the purpose of performing clinical trials necessary to obtain 'MAs' for the generic drug. Polpharma had also stated that the active ingredient would be delivered to the purchasers only with the condition that it would then be used exclusively for the purpose of conducting clinical trials in order to obtain the 'MA'.

The German Court of Appeal, having doubts about a restrictive interpretation of the rule, according to which the clause would apply only to the applicant for the "MA". who would therefore also have to take care of all operations in the chain, including the production of the active substance, had referred the matter to the European Court of Justice for a ruling (C 661-13).

In the course of the proceedings, Astellas later withdrew the case, and therefore the European Court of Justice has not ruled further.

2.9. The Court of Milan and the Court of Appeal, in judgment no. 1785/2021, appealed against here, while holding that the Bolar exemption applies not only to the person who independently produces the active ingredient, carries out the necessary experiments to apply for the marketing authorisation and then applies for the marketing authorisation, but also to third party producers of active ingredients who do not subsequently apply for the marketing authorisation, but who supply the active ingredient to those who intend to apply for it, so as to put them in a position to do so, thereby proposing a broader interpretation with respect to the subjective scope of application of the exception, they held that this objective scope should, however, be applied only when the producer of the patented active ingredient and the applicant for the MA, who subsequently uses it for study and experimentation activities, pursue the same purpose, i.e. obtaining a MA for a pharmaceutical product; Thus, the case in which the production/offering of the product is objectively unrelated to the purpose of obtaining a marketing authorisation and the profit that the manufacturer derives from the sale of the product is the remuneration of an activity of study and production, offering and advertising, or of an activity of commercial exploitation of the patented principle, was held to be unlawful, since this activity cannot be covered by the exemption in question.

It should be recalled that the restrictive thesis (expressed in a number of judgments on the merits), with regard to the subjective scope, identifies the rationale of the 'experimental exception' in the impossibility for the experimenter to derive a direct profit from his research activity in any case, since this must be understood as mere research aimed at overcoming and/or

improvement of the invention, without direct profit and without prodromal activities for sale or production in quantities incompatible with experimentation alone.

2.10. Well, the interpretation given by the Milanese court is first of all contrary to the letter of the rule.

It must indeed be considered that the exception under the Bolar clause with respect to the exclusive rights of the patent holder certainly concerns the activities of study and experimentation, preparation and use of pharmacologically active raw materials by the party seeking its own marketing authorisation.

Thus, according to the letter of the provision in Article 68(1)(b) of the Code of Criminal Procedure, mere production and marketing activities carried out by a third party are not excused.

The counter-appellant hits the nail on the head when it observes how the appellants contradictorily, on the one hand, support a broad interpretation - and therefore necessarily going beyond the textual data - such as that made by the Court of Appeal, on the point of application of the Bolar exception to producers of active ingredients, and, on the other hand, assume that such an interpretation should instead be strictly literal, when it comes to identifying the conditions and prerequisites for such broad application.

Quite correctly, however, the Court of Appeal (and the Court before it) pointed out that Art. 68(1)(b) IPC must be interpreted in such a way as to achieve a balancing of opposing interests, i.e. the interest in avoiding delays in the market introduction of generic drugs, once the patent/CCP has expired, on the one hand, and the interest of the patent or CCP holder in preserving and protecting its exclusive rights to the invention, on the other.

In essence, the objective pursued by the legislator, including the European legislator, is to make lawful the activities necessary for the submission to the competent authorities of an application for a marketing authorisation for a generic drug, even if they involve the use of someone else's patented invention, and to enable manufacturers of generic drugs to be in a position to place their products on the market in the shortest possible time, after the expiry of the patent, by avoiding that the holder of the pharmaceutical patent, to whom the system already allows, through the mechanism of the supplementary protection certificate, to recover, by means of an extension of protection, the time taken to obtain the marketing authorisation, enjoys, once his patent has expired, a further de facto extension of the exclusivity regime, in relation to the time taken by the generic manufacturer to obtain a marketing authorisation for the generic drug.

And, moreover, Art. 68(1)(b) of the C.P.I. does not require the applicant for the 'MA' to have directly manufactured the active ingredient or directly carried out the testing activities.

By virtue of the rationale of the rule, regard must therefore be had, rather than to the person engaging in the conduct exempted from liability, to the purpose of the trials necessary to introduce generic drugs onto the market relatively quickly, which characterises the Bolar exception.

Consequently, having to look at the purpose of the Bolar exception (the obtaining of an "AIC" in a more rapid time frame, compatible with those of the pharmaceutical sector), even though it may also apply to the producer of active ingredients that performs study/experimentation/production activities for the registration purposes, not its own, but of a third generic manufacturer, it is necessary, in this case, that the Bolar purpose is clear ab origine and that therefore, upstream of the activity of production and marketing of the active ingredient there is a "commissioning" relationship, by virtue of which the manufacturer is approached by the generic third party "for a study, production and delivery activity that is in turn lawful insofar as it is ex ante inherent to the aforesaid purpose" and the manufacturer acts "only by reason of a request supported by a declared purpose capable of exculpating its conduct expressly contemplated - as a limit of use - in the relative negotiating regulation".

The activities exempted by subparagraph (b) of Art. 68 are those for the purpose of submitting a marketing authorisation for a drug, and that purpose must be apparent, if the activity is carried out not for its own but for a third party's registration purposes, ex ante and unequivocally.

In the absence of a request by the party, the production/offer of the product is unrelated to the purpose of obtaining an 'AIC' and the profit that the manufacturer derives from the sale of the product is the remuneration of an activity of study and production, offer and publicity, i.e. of an activity of mere commercial exploitation of the principle patented by others, which took place without any coverage of the exculpatory nature.

Only a person who manufactures active ingredients or samples on behalf of a client who can make use of Bolar (for registration purposes as described above) cannot be considered an infringer of another's industrial property right, even if he receives remuneration for the service rendered to others.

Nothing then prevents the company producing active ingredients from advertising its activity in general terms, so that the generic manufacturer - interested in a specific active ingredient - can contact that company to see whether or not it is interested in producing (on its behalf) that specific active ingredient.

It is true that the small generic manufacturer (and therefore not endowed with its own operational structures) interested in filing and being granted an 'MA' application for its own generic drug, in advance of the patent or 'CCP' expiry date, will have to take action in good time, even several years in advance, by making a special request to a third-party manufacturer that can study and then produce the active ingredient necessary for registration purposes.

But the timeframes associated with the production of an active ingredient that the generic manufacturer 'with an in-house production facility' will have to face (including those necessary to obtain the various regulatory authorisations) are the same as those faced by the third-party manufacturer approached by the small generic manufacturer.

And, again in the functional-teleological perspective of the extensive interpretation (it is repeated, however favourable to the appellants, with respect to a literal interpretation), correctly, the territorial Court held that in order for it to be affirmed that the Bolar purpose connotes the activity of the manufacturer of the active ingredient ab origine, it is necessary, in addition to the prior request by the generic manufacturer, also that such registration purpose be indicated at the negotiation level as a limitation of use, as a provision of the commitment to use the active ingredient according to the Bolar purpose, supported by the agreement to pay a penalty in the event of breach of the commitment.

These are minimum precautionary measures to avoid uses of the active substance that are not covered by the exception.

Ultimately, in order for the Bolar exemption to also apply to those who produce the active ingredient protected by the patent not in order to obtain the 'AIC' directly, but to sell it to a third party (the generic manufacturer) who will use it for that purpose, the Bolar purpose must be unambiguous and can be adequately proven to be present ab origine. The correct interpretation of the rule of law is so clear that it leaves no room for reasonable doubts of interpretation.

And those necessary conditions were not proved by the appellants in the judgment on the merits, a finding of fact that cannot be reviewed in this court.

With regard to the circumstance, noted in the two pleadings filed by the applicants, relating to the reformulation, in the proposal for the reform of European pharmaceutical legislation published by the European Commission on 26 April 2023, of the Bolar exemption at European level, the following brief remarks must be made.

It is inferred, in particular, that: a) in the 'Proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use', in Article 85, entitled 'Exemption to the protection of intellectual property rights', a reformulation of the Bolar exemption at European level was proposed in the sense of exempting 'any activity (including information and offering to third parties ("offer"), production

("manufacture"), sale and supply ("sale" and "supply"), whether carried out by the company directly involved in the testing activity, or by third party suppliers, and in the latter case without any limitation or pre-conditions"; b) lastly, on 10 April last, the European Parliament approved the Commission's proposal for a directive at first reading, confirming the list of activities envisaged to be included within the Bolar exemption, as well as the subjective extension to "third party suppliers".

And it is deduced that it would be "unreasonable as well as anachronistic" to adopt today an interpretation of the Bolar exemption "completely at odds with the interpretation that the European legislator is giving of it".

The applicants themselves represent that Recital 63 of the new proposed directive ('...it is considered necessary, in order to facilitate the entry onto the market of generic medicinal products ... which are based on a reference medicinal product, to clarify its scope in order to ensure harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered') specifies precisely that the proposed amendment is intended to clarify the scope of Bolar, both in subjective terms and in terms of activities covered, in order to ensure the timely entry onto the market of all generic manufacturers, without any discrimination.

This Court observes, in that regard, that, apart from any finding as to the clarity and unambiguousness of the interpretation of the new provision in the sense sought by the appellants (and not also in the sense of providing that the Bolar exemption is to apply only to conduct carried out exclusively for the purpose of conducting clinical studies with a view to obtaining a marketing authorisation) it is a new rule, not yet approved and not applicable ratione temporis to the present case, even if it were approved, which, if anything, confirms to the contrary that the rules previously in force did not allow the extension of the Bolar exemption without limits and conditions.

The following principle of law must therefore be affirmed: "On the subject of limitations of patent rights and the interpretation and application of Article 68(1)(b) of the Industrial Property Code, as set out in Legislative Decree No. 30 of 10 February 2005, the result of the transposition into Italian law of Directive 2001/83/EC (Art. 10.6), later amended in Directive 2004/27/EC, the rationale of the so-called "Bolar clause" or "Bolar exemption", according to which the activities of testing a drug covered by another person's patent, aimed at obtaining an administrative authorisation to market the drug, which is intended to operate after the expiry of the other person's patent, are allowed, is to facilitate the timely entry of generic drugs on the market in order not to prolong, de facto, the duration of the patent, allowing generic manufacturers to begin the administrative and testing activities prodromal to obtaining a marketing authorisation, even while the reference patent remains in force, by introducing limits to the right of exclusivity; the Bolar exception or exemption may

be deemed applicable also to the activity of third parties who produce the active ingredient of the patented drug, for registration purposes not of their own but of third-party generic manufacturers, not equipped to produce on their own, but intent on entering the market, upon the expiry of the exclusivity of the patent title; however, this broad interpretation of the exception presupposes, in order for it to be affirmed that the Bolar purpose connotes the activity of the producer of the active ingredient ab origine and ex ante, in addition to the prior request by the generic manufacturer, also that this registration purpose is indicated at the negotiation level as a limitation of use, as a forecast of the commitment to use the active ingredient according to the Bolar purpose".

3. For all the foregoing, the appeal must be dismissed. The costs, awarded as set out in the operative part, are to be shared.

P.Q.M.

The Court dismisses the appeal; orders the appellants, jointly and severally, to reimburse the costs of the present proceedings, awarded in the total amount of Euro 8,000.00, by way of fees, plus Euro 200.00 for disbursements, as well as a fixed reimbursement of general expenses, at the rate of 15%, and legal accessories.

Pursuant to Article 13, paragraph 1-quater of Presidential Decree 115/2002, it acknowledges the existence of the procedural requirements for the payment by the applicants of the amount of the unified contribution, equal to that due for the appeal, where due, pursuant to paragraph 1-bis of the same Article 13.

Thus decided, in Rome, in the council chamber of 12 June 2024.

Filed at the Registry on 5 July 2024.