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 the Honorable Magistrates:
Dr. SCOTTI Umberto Luigi Cesare Giuseppe - President
Dr. MARULLI Marco - Councilor
Dr. IOFRIDA Giulia - Councilor - Rel.
Dr. TERRUSI Francesco - Councilor
Dr. FALABELLA Massimo - Councilor
pronounced the following

JUDGMENT

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

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 lawyers BIAMONTI LUIGI (omissis), BERGIA STEFANIA
(omissis), SIRONI GIULIO ENRICO (omissis);
- plaintiffs -

versus

Bo.In. PHARMA GMBH AND CO. KG, electively domiciled in ROME VIA TOSCANA 1,
at the office of lawyer CERULLI IRELLI GIUSEPPE (omissis) who
represents and defends her jointly 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 the
Councilor GIULIA IOFRIDA.
Having heard the counsel for the applicants, Attorneys Bergia and Sironi, and the

Counterclaimants, Attorneys Trevisan and Cerulli Irelli, who orally presented
The conclusions of the respective acts.
Hearing the Attorney General, Dr. Andrea Postiglione, who concluded for the
Dismissal of the appeal.

CAUSE FACTS.

The Court of Appeals of Milan, in Judgment No. 1785/2021, published on 8/6/2021, upheld Judgment No. 8273/2018 of 24/7/2018 of the Court of Milan, in which - in proceedings instituted, in May 2014, at the outcome of precautionary 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, to ascertain the infringement of 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 judgment, it had been ascertained and declared, in upholding the main claims of the plaintiff company Bo.In., that the production, marketing, import, export, distribution, and advertising by the defendants of tiotropium bromide in any form, including the anhydrous and monohydrate forms subject to judicial description (on the basis of the purely pharmacological CTU prepared by Prof. Ca, in relation to an activity of production and sale by Sicor of quantities of tiotropium bromide compatible with the production of industrial-scale batches of a generic version of the product SPIRIV), had constituted infringement of the Italian portion of the patent EP 716 (expired on 12/9/2010) and CCP 849 (expired in September 2016), as well as an act of unfair competition, and it was ordered that the case be remitted to the role by virtue of a separate order, in order to continue the preliminary investigation phase with regard to the claim for damages.

In particular, the subject of the dispute, which is still of interest in this court of legitimacy, concerned the interpretation of Article 68, I paragraph, letter b) c.p.i., the result of the transposition in Italy of Directive 2001/83/EC (Art. 10.6), later amended in Directive 2004/27/EC, which states: "the exclusive right conferred by the patent does not extend, whatever the subject matter of the invention: ... (b) to studies and experiments aimed at obtaining, including in foreign countries, a marketing authorization for a drug and the consequent practical steps including the preparation and use of pharmacologically active raw materials strictly necessary for that purpose") (so-called. "Bolar clause," a U.S.-

based principle stemming from the litigation between Roche and Bolar concerning the infringement of patent related to the active ingredient Flurazepam, in the former's availability and resulting, then, in the regulatory intervention aimed at liberalizing the trials necessary to obtain marketing authorization).

The Court pointed out, on the one hand, that the rationale behind this clause is to facilitate the timely market entry of generic drugs so as not to prolong, in fact, the duration of the patent, allowing generic manufacturers to begin the administrative and testing activities prodromal to obtaining a MA, even while the reference patent is in force, thus being introduced limits to the right of exclusivity, and, on the other hand, that this is a rule of strict interpretation that, while not allowing, pursuant to Art. 14 preleggi, the analogical interpretation, admits, however, the extensive interpretation, always with a view to the balancing of, 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 of first instance, in the face of Bo.In.'s argument. according to which the Bolar exception could apply only to those entities that, internally, carry out activities of preparation and use of the active ingredient in order to prepare documentation for their own application for marketing authorization of the drug (AIC), that: (a) the Bolar clause cannot apply to mere producers/resellers of active ingredient, i.e., those who carry out experimentation and production activities not aimed at obtaining a MA, but aimed at obtaining the active ingredient covered by the patent and offering it for sale to others; (b) however, the exception is also applicable to the activity of third parties who produce the active ingredient of the patented drug, for registration purposes not their own but of third parties and at the request of such genericists, who are not equipped to produce on their own, but intend to enter the market, upon the expiration of the exclusivity of the patent title, because, in such cases, "the activity of the third party is closely combined with that of the genericist who intends to obtain the AIC and the profit he makes from it constitutes remuneration for the service rendered, making available his skills, experience and technological tools," and in fact the provision of Art. 68, paragraph I, lett. a) c.p.c. admits experimental activity insofar as it is commissioned to third parties in exchange for a fee; c) "the Bolar exception, although it could also be applied with regard to the activity of subjects producing the active ingredient for registration purposes not their own but of others, presupposed, in any case, that such production and marketing activity was carried out at the request of genericists 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, putting in place 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 should have acted at the request of the genericist and not proposed itself for the search of potential customers; furthermore, the companies themselves had not taken any precautionary measures aimed at preventing the active ingredient offered and sold from being used for purposes unrelated to the "Bolar clause."

The Court of Appeals, ruling on the only ground of appeal brought by Sicor and Teva against the partial judgment of first instance, premised that, as correctly held by the court of first instance, the "Bolar clause," was a provision of an exceptional nature, aimed at allowing "the performance of all those activities, experimental and administrative, having a preparatory function with respect to the marketing authorization of generic products, i.e., of products containing the same active ingredient as medicines for which patent exclusivity on the active ingredient has expired," conferring "greater rapidity in the entry of generic drugs on the market, since the genericist is not obliged to complete all the clinical studies aimed at demonstrating the efficacy and safety of the product, relying on the studies already carried out in relation to the reference drug, the so-calledd. originator," deemed correct the interpretation offered by the Tribunal, according to which the Bolar clause cannot apply to mere producers/resellers of active ingredient, in a trade-off between the freedom of economic initiative in a particularly significant sector for the global community that of pharmaceuticals and the necessary protection of the owner of the patent. Consequently, genericists lacking the necessary technological equipment and expertise may turn to third-party producers of the active ingredient to request a production and delivery activity, which is to be considered legitimate insofar as it is functional to obtaining an MA, but "the activity of the third-party producer, since it cannot be released from a specific request by the genericist, cannot include a true marketing activity...contrary to the experimental and registration purposes typical of the exception permitted by the legislative provision."

In the concrete case under consideration: (a) Sicor and Teva, not specifically challenging this interpretation of the provision, admitted in their own acts that they had started the activities of production and advertising of tiotropium, prior to and independently of a specific request and assignment by a genericist company, in contrast precisely with the also extensive interpretation admitted by the first instance 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 genericist customers; c) as to the warnings addressed to genericists, about being able to sell only for Bolar purposes, on the website (omissis), the disclaimer was inserted in 2014, after the July 2013 description, while it did not appear in the 2012 product catalog and was removed in the 2015 catalog, as admitted by the defendants themselves, albeit in error, and in any case referred in general to all products, not specifically to the tiotropium principle;

(d) the correction about the authorization requested from AIFA, to the production of tiotropium bromide for the purpose of clinical trials only, even, but obtained by mere error for commercial purposes, could not legitimize the advertising and marketing carried out via the Internet; (e) these conclusions made it superfluous to examine whether the quantities of tiotropium bromide were compatible with the purpose of marketing in order to exclude it, so as to deem the Bolar exemption complied with, and even more superfluous was the examination of the question of the quantity of active ingredient sold in Turkey to the Turkish company Neutec, in that the constituent elements of the Bolar exception did not appear to be integrated "once it is admitted that Sicor and Teva produced tiotropium bromide on their own initiative, offering it indiscriminately for sale, in the absence of stringent and clear negotiating clauses and in the absence of as many punctual negotiating regulations suitable for ensuring exclusively registrational use since 2012."

In conclusion, the Court of Appeals, upholding the first instance decision and rejecting the appeal, stated that "the manufacturer of the active ingredient, in order to benefit from the Bolar clause exception, must show that it has acted on the input of a genericist entity and that it has adequately regulated and guarded by negotiation (e.g, with the provision of a penalty) the fact that the genericist will use the active ingredient only for Bolar purposes," and that "in the absence of these conditions, the quantities of the active ingredient made and sold by the manufacturer appear to be completely irrelevant, and this is all the more so given the extreme variability of the quantities required for the experimental/registration phase."

Against the aforementioned ruling Sicor Srl and Teva Pharmaceutical Industries Limited appeal for cassation, served on 10/1/2022, on a single ground, against Bo.In. Pharma GmbH E Co. KG (which resists with a counter-appeal served on 2/21/2022).

Both parties filed briefs.

By Interlocutory Order No. 21679/2023, the case was adjourned from the chamber meeting on 5/23/2023 for hearing in open court.

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

The appellants and the respondent have filed additional briefs.

At the public hearing on June 12, 2024, counsel for the parties were heard, who orally explained their respective acts, and the PG, who concluded for the dismissal of the appeal.

Computer-assisted translation of the judgment

REASONS FOR THE DECISION

1. The appellants complain, in a single plea, of violation or false application of Article 68, co. 1, lett. b), c.p.i. in relation to Article 360, co. 1, no. 3, c.p.c, censuring the judgment of the Milan Court of Appeals for holding that the exception under art. 68, co. 1, lett. 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 in response to a specific request from the genericist concerned and (b) the producer engages in a series of behaviors that are neither expressly mentioned, nor implicitly required, by the rule in question.

The Sicor and Teva companies, while agreeing with the extension by interpretation of the group of parties who, in view of the rationale of Article 68 under examination, can take advantage of the Bolar exemption (including third parties who produce the patented active ingredient, in order to supply it to genericists who are not equipped to produce it on their own, but intend to enter the market upon the expiration of the exclusivity of the patent title, so as to allow such genericists to take advantage of the activity of mere external producers in order to gain timely access to the procedures for granting AICs), they contest the unacceptable "creative" interpretation made by the judges of merit, through the addition of a series of stringent additional requirements and 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 start of production (and, even before that, of the experimental activities necessary to prepare an adequate production process) only upon request of the third genericist and b) the stipulation of "adequate" contracts committing the third genericist to compliance with the Bolar exemption."

This is, for the applicants, an unfairly additive interpretation, as well as illogical and impossible to apply in practice.

The judgment under appeal, the appellants argue, in prohibiting the manufacturer of active ingredients from informing third parties of its ability (in terms of skills, machinery, personnel,...) to produce a particular active ingredient "before it has received a request for supply," would render the Bolar exemption practically inapplicable, based on 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 genericists interested in commissioning the production of an active ingredient would have to sound out the availability of an indefinite number of possible producers before finding one available"; c) "alternatively, the genericist would be forced to approach active ingredient producers who 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 can well begin, well in advance of the receipt of requests for supply (also in relation to the long time, at least three years, required for the "fine-tuning of the production process - necessary for the purpose of the supply of an active ingredient characterized by a sufficient degree of purity", to which must be added the time - about a year - imposed by the 'bureaucratic process required to obtain an authorization for the production of the active ingredient for experimental and clinical use, necessary in order to be able to start production of the active ingredient precisely at the experimental end), to produce "under Bolar conditions" the active ingredient even in the absence of requests from genericists, having the manufacturer itself very clear that the (eventual) supply of that active ingredient will take place precisely only under the same Bolar conditions and will be aimed at carrying out the activities of application for AICs by those genericists.

Otherwise, the interpretation of the lower courts - in essence, repealing - would have precisely the effect of restoring "that unjustified discriminatory treatment - criticized, inter alia, also by the first instance judgment12 and in any case contrary to Art. 10.6 of Directive 2001/83/EC - between genericists with adequate production facilities (i.e., the economically stronger genericists, who could start at any time the activities of production of the active ingredient and then the activities necessary to obtain an MA) and genericists without the facilities in question (thus, genericists 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 Appeals, in violation of Article 115 c.p.c., would also have misinterpreted the statements of Sicor and Teva, which have always "stated that the experimental activities initiated by Sicor were intended to enable one or more Teva Group companies (thus, technically, third-party genericists) to obtain an AIC," and that the activities in question "therefore still started after receiving an application from a company-third party to Sicor."

The challenge about the additive interpretation made by the trial judges is also directed with reference to the second condition, identified under (b), that is, the need for the prior stipulation of "appropriate contracts committing the third-party generic supplier to compliance with the Bolar exemption."

If the sole condition of lawfulness is the (to be assessed ex ante) experimental and registration purpose (and thus the fact that the manufacturer intends to produce and supply the active ingredient to enable third-party genericists to obtain the necessary AICs), no relevance can be attached to the final (ex post) decision of the third-party genericist about the use of the active ingredient in question. Moreover, a private negotiated agreement (even if backed by a penalty) could in no way guarantee that the

third-party genericist would refrain from committing acts of counterfeiting, and in any case the active ingredient manufacturer could not be blamed for this, especially when - as in the present case - it made efforts, through disclaimers letters signed by customers, warnings on products and delivery notes, to warn the third generic manufacturer - at the time of supply but also before, that is, already at the time of the information activity on the availability of the active ingredient tiotropium bromide - of the only purpose for which the active ingredient was allowed to be used.

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

"(1) Is Article 10(6) of Directive 2001/83/EC to be interpreted as meaning that the exclusion of patent protection (possibly extended through a supplementary protection certificate) for acts by which a third party offers or supplies to a generic company a patent-protected active ingredient that the generic company planned to use to carry out studies and trials for the purpose of a marketing authorization for medicinal products under Article 10(6) of Directive 2001/83/EC requires:

(a) that the third party wait until it receives a specific supply request from the generic company before initiating any preparatory activities, including, for example, the activity of informing about the third party's readiness to supply that active ingredient, the activity of preparing internally a manufacturing process for that active ingredient, the activity of preparing the Drug Master File related 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 precise contractual agreements with each generic company 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 means (e.g. penalty clause, indemnity clause,...); and (ii) the generic company agrees to use the active ingredient exclusively for registration purposes."

1.3. The counter-appellant first of all objects to the inadmissibility of the plea, noting that there can be no reconsideration of the interpretation of Article 68, paragraph 1(b), I.P.C., in a sense possibly more favorable to Sicor/Teva, this interpretation having become final, as noted by the Court of Appeals in a ruling also not challenged by the appellants.

The exception is unfounded.

Indeed, the Court of Appeals acknowledges that Sicor and Teva "expressly agreed with the interpretation of the Bolar clause as set forth by the trial judge, thus with an adequate appreciation of the teleological perspective underlying Article 68,paragraph 1(b) c.p.i.", but disagreed, on the other hand, "with the factual assessment of the

violation of the exemption clause," except then clarified that the requirements that, in the opinion of the court, the Bolar clause, in order to satisfy the declared registration purpose, had to present were 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 the limit of use.

Thus, the interpretation of the so-called Bolar exception as offered by the Tribunal had been appealed on appeal, and there can be no question of an internal ruling precluding consideration of the plea.

Nor can it be held that the Court of Appeals, having nevertheless deemed to examine the objections raised by Sicor/Teva "and deemed (by Sicor/Teva, ed.) not adequately valorized by the Court, in the light of which the production of the active ingredient should be considered covered and endorsed by the Bolar clause," would have ascertained, with an independent ratio decidendi (with respect to the interpretation of the Bolar exception adopted), that Sicor/Teva had not produced and marketed "tiotropium bromide" at the request of genericists but on their own initiative, verifying, however, also the concrete ways in which "tiotropium bromide" was advertised and offered for sale adopted by Sicor/Teva, so as to rule out, in any case, that even an interpretation of the clause, in line with that asserted by the other party (according to which the activity of the third party producer of active ingredients could be considered to be exculpatory even when the same acts on its own initiative, and not upon input from the genericist), could have led to a successful acceptance of the opposing appeal.

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

1.4. The counterclaimant then argues that the plea is inadmissible due to lack of interest.

This is because the appellants' argument, according to which it would be totally irrelevant that the conducts of the active ingredient manufacturer are preceded by a specific request from the genericist, "the manufacturer itself having made it very clear that the (eventual) supply of that active ingredient will take place precisely only on the same Bolar conditions and will be aimed at carrying out the activities of applying for AICs by those genericists." would lack the necessary factual prerequisites, as no

evidence emerged in the trial court that the offer for sale and supply took place "on Bolar conditions" and was aimed at carrying out the AIC application activities by those genericists.

The exception is, likewise, not worthy of acceptance.

Indeed, the assumption of the plaintiffs is that they can take advantage of the Bolar exemption, as third-party manufacturers of the patented active ingredient, to supply it to genericists who are not equipped to produce it on their own, but intend to enter the market upon the expiration of patent title exclusivity in order to obtain the necessary MAs, and that they may initiate the experimental activities necessary to prepare an adequate production process, regardless of a prior request from the third genericist and the stipulation of appropriate contracts committing the third genericist to compliance with the Bolar exemption or specific arrangements by said third manufacturers (notices , disclaimers, etc...).

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

2.1. Art.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 November 3, 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 power conferred by the patent right does not extend, whatever the subject matter of the invention:

(a) to acts done privately and for non-commercial purposes; (a-bis) to acts done experimentally 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) to studies and experiments aimed at obtaining, including in foreign countries, a marketing authorization for a drug and the consequent practical requirements including the preparation and use of pharmacologically active raw materials strictly necessary for this purpose;

(c) to the extemporaneous preparation, and per unit, of medicines in pharmacies on prescription, and to medicines so prepared.

(c-bis) to 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 Art. 68 of the previous c.p.i., following the amendments introduced by Legislative Decree 131/2010, read as follows:

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

(a) to acts done privately and for non-commercial purposes, that is, on an experimental basis;

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

(c) to the extemporaneous preparation, and per unit, of medicines in pharmacies on prescription, and to medicines so prepared, 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 power conferred by the patent right did not extend, whatever the subject matter of the invention, (a) "to acts performed privately and for noncommercial purposes, that is, experimentally even though they are aimed at obtaining, including in foreign countries, a marketing authorization for a drug and the consequent practical steps including the preparation and use of pharmacologically active raw materials strictly necessary for that purpose."

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

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

2.2. It should be recalled that already the Inventions Law set forth in Royal Decree No. 1127/1939, as amended by Presidential Decree No. 338/1979, contemplated in the third paragraph of Article .1 : "The exclusive power conferred by the patent right does not extend, whatever the subject matter of the invention may be: 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 so prepared."

It should also be pointed out that, in the drug sector, in order to bridge the time between the date of filing the patent application and the date of marketing authorization, a time necessary for the due complex verifications but which delays the exploitation of the invention, by Law No. 349 of October 19, 1991 (which resulted in the addition, in the body of RD 1127/1939, of Art. 4-bis) was introduced, for the first time in Italy, the "complementary certificate of protection," CCP for short, in order to meet the requests of the pharmaceutical industry to extend the duration of patent protection (as a rule, equal to twenty years from the filing of the patent application), in the field of medicinal specialties, so as to be able to make up for the time lost in the commercial exploitation of the invention, until the indispensable Marketing Authorization, in short AIC (through registration by the Ministry for the Interior ex art. 162 T.U. Health Lawsen. 1265/1934, as replaced by Art. 4 of Law 422/1941), also necessitating considerable scientific, technical and financial efforts.

Indeed, Article 4-bis of the Invention Law 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 by which the first marketing authorization of the medicine is granted," up to a maximum of eighteen years.

2.3. At the European level, on June 18, 1992, the EEC Regulation No. 1768/1992 was then issued, in order to minimize the discrepancies created by the different national regulations of the member states and to protect the European pharmaceutical industry (especially in the face of the protection introduced by the U.S. and Japanese regulations) by ensuring a common discipline for all European states, which came into force, simultaneously in all Community countries, on 2/1/1993, resulting in the absorption of the previous Italian discipline; according to Art. 1 of Regulation No. 1768/92, holders of a patent for an invention, having for subject matter "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"), always after it had obtained registration for the purpose of marketing the medicament itself.

The EU legislature therefore introduced a discipline of "SPCs" (an acronym for Supplementary Protection Certificate, also called in Italy "CPC," short for Certificato Protettivo Complementare) in the field of medicinal specialties (and later also of plant protection products) to " give the inventor of the drug, in addition to the patent a

'complementary' patent aimed at prolonging the duration of the exercise of the exclusive exploitation rights of the invention in order to compensate at least partially for the years elapsed between the issuance of the patent title and the marketing of the drug, which requires the performance of controls by the Public Administration."

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

To resolve some 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. Indeed, in recital No. 13, of the said Regulation, it is stipulated that "the certificate confers the same rights as the basic patent."

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

2.4. The EU legislature then regulated, in Directive No. 2004/27/E.C., amending Directive No. 2001/83/E.C., known as the European Medicines Code, the manner in which MAs or MAs are granted.

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

Correctives have been inserted at the European level, in a pro-competitive logic 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 need underlying this prolongation, without imposing additional limitations on independent producers: 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 that is made in implementation of what constitutes the "heart" of the patent, a delay due precisely to the regulatory procedures that, 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 expiration 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 Authorization ("MA"). The time extension covers the active ingredient claimed by the patent and present in the authorized drug.

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

2.5. The Agreement on the Unified Patent Court, 2013/C 175/01, in Article 27, Paragraph 1, "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) to acts done experimentally relating to the subject matter of the patented invention;..."

On July 1, 2019, the discipline of the so-called "SPC Manufacturing Waiver" entered 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 an "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 expiration of the certificate. This is in order to a fill the "competitive disadvantage" of European manufacturers of generic drugs vis-à-vis manufacturers operating in third countries where the complementary protection offered is less or completely absent.

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

All, with a view to marketing the generic drug immediately after the patent expires.

It should only be recalled that, back in 2002, our legislature had already tried (with Decree Law No. 63/2002, converted into Law 112/2002) to introduce, alongside a gradual reduction in the duration of the "CCPs" still in force, also the express provision of the option for "companies intending to produce pharmaceutical specialties outside

patent coverage" to "initiate the registration procedure for the product containing the active ingredient in advance of one year before the expiration of the complementary patent coverage of the active ingredient."

It should be pointed out that Legislative Decree 219/2006, implementing Directive 2004/27/EC, also stipulates 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 219/2006 and the Directive, as to the drugs, which are the subject of the application for marketing authorization, refer only to the studies and trials necessary for the purpose of applying the paragraphs regulating one of the "special" authorization regimes concerning generic drugs, biosimilars, and so-called "hybrid" drugs, not also "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 relating to "Flurazepam," on the grounds that Bolar, several months ahead of the patent's expiration date, had procured from a foreign manufacturer a small quantity of the product for the purpose of conducting the studies and experiments necessary to submit to the U.S. Food and Drug Administration (FDA) the application for marketing authorization of the corresponding generic (Paper New Drug Application). In the first instance, Bolar succeeded in prevailing, in view of the recognized experimental nature of its activity and the marginal nature of it. On appeal, however, the Court of Appeals for the Federal Circuit overturned the first decision, holding that in any case the use of a patented drug conducted for the sole purpose of obtaining authorization to market the corresponding generic did not fall within the experimental use exception and therefore constituted infringement, as it could not therefore be carried out before the patent expired. The U.S. legislature had then 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 making legitimate experimental activities directed at obtaining market authorization (MA) of a generic even when they involve the implementation of a patent still in force.

The name "Bolar Clause" has therefore, since then, been used to designate the rules that stipulate that patent exclusivity cannot be opposed to activities, not authorized by the patent owner, if they are directed to obtaining marketing authorizations 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 directed at proving that the generic has 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 Drug Code, introduced the Bolar exemption in Europe.

Thus, the patent holder cannot oppose the completion of prodromal activities for obtaining a marketing authorization ("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 subparagraph (b) (referring to "studies and experiments aimed at obtaining, including in foreign countries, a marketing authorization for a drug and the consequent practical steps, including the preparation and use of pharmacologically active raw materials strictly necessary for that purpose") from the hypothesis of subparagraph (a) (concerning acts performed "experimentally"), is in the sense that, for the purpose of configuring the exception under consideration, it is not the purely experimental nature, but the purpose of obtaining the "MA" that makes the contemplated activities lawful even when the drug is still covered by a patent or supplementary protection certificate.

2.8. It is not in dispute that the rationale behind the Bolar clause is to facilitate the timely entry of generic drugs into the market in order not to "de facto" prolong the duration of the patent protection, since with said exemption it is possible to carry out all the administrative and testing activities prodromal to obtaining an "AIC" while the reference patent is still in force.

The EU 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 businesses which, upon the expiration of the patent, have the right to the full and immediate re-expansion of freedom of economic initiative by intending to compete on the market with the owner of the same.

Art. 68 c.p.i., or the so-called Bolar clause, introduces limits to the right of exclusivity that patent ownership confers, justified by distinct needs deserving of overriding protection; limits that constitute, therefore, exceptions to the rule of the fullness of patent rights, which, in the absence of the regulatory provisions under comment, would require that the conduct provided for therein be qualified as infringement.

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

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

The interpretation of the European Directive was the subject of a dispute involving, between 2011 and 2013, 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 over the production of the active ingredient "solifenacin succinate," which fell within the scope of protection of the Astellas patent. 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 Germany, and Polpharma, in its defense, 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 for obtaining "AICs" for the generic drug. Polpharma had also claimed 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 performing clinical trials in order to obtain "AICs."

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

During the pendency of the proceedings, Astellas later withdrew the case, and thus the ECJ did not rule further.

2.9. The Court of Milan and the Court of Appeals, in ruling no. 1785/2021, appealed here, while holding that the Bolar exemption applies not only to the person who independently produces the active ingredient, carries out the experiments necessary to apply for the MA and then applies for the MA, but also to third party producers of active ingredients who do not subsequently apply for the MA, 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 an expansive 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 testing activities, pursue the same purpose, namely, obtaining an MA for a drug; thus, the case where the production/offer of the product is objectively unrelated to the purpose of obtaining an AIC and the profit that the manufacturer derives from the sale of the same is the remuneration of an activity of study and production, offer and publicizing or an activity of commercial exploitation of the patented principle, has been deemed unlawful, since this activity cannot receive any coverage from the exculpatory act under consideration.

It should be recalled that the restrictive thesis (expressed in some meritorious pronouncements), 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, this having to be understood as mere research aimed at overcoming and/or improving the invention, without a direct profit and without prodromal activities for sale or productions in quantities incompatible with experimentation alone.

2.10. Well, first of all, the interpretation given by the Milanese court is not contrary to the letter of the rule.

Indeed, it should 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 to obtain its own marketing authorization.

Therefore, mere production and marketing activities put in place by a third party are not, according to the letter of the provision in Article 68(1)(b) of the I.P.C., to be excused.

And it hits the nail on the head when it observes how the appellants, contradictorily, on the one hand, support an extensive interpretation - and therefore necessarily beyond the textual datum - such as that made by the Court of Appeals, on the point of application of the Bolar exception to subjects producing the active ingredient, and, on the other hand, assume that such an interpretation should instead be strictly literal, when it comes to identifying the conditions and prerequisites of such extensive application.

Quite correctly, on the other hand, the Court of Appeals (and before that, the Tribunal) pointed out that Article 68(1)(b) ICC 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 legislature, including the European one, is to make lawful the activities necessary for the submission to the competent authorities of an AIC application for a generic drug, even if they involve the use of someone else's patented invention, and to allow manufacturers of generic drugs to be in a position to put their products on the market in the shortest possible time, after the patent expires, avoiding that the holder of the pharmaceutical patent, to whom the system already through the mechanism of the supplementary protection certificate allows to recover, with an extension of protection, the time taken to obtain the granting of the marketing authorization, enjoys, after the expiration of his patent, a further de facto extension of the exclusivity regime, in relation to the time taken by the generic manufacturer to obtain an "AIC" on the generic drug.

And, moreover, Article 68(1)(b) c.p.i. does not require that the applicant for "AIC" has directly manufactured the active ingredient or directly performs the testing activities.

By virtue of the rationale of the rule, therefore, regard must be had, rather than to the subject who engages in the conduct exculpatory, to the purpose of the trials necessary to introduce generic drugs to the market relatively quickly, which characterizes the Bolar exception.

Consequently, having to look at the purpose of the Bolar exception (the obtaining of an "AIC" in a faster timeframe, compatible with those of the drug sector), although it may also apply to the producer of active ingredients who carries out study/experimentation/production activities for the registration purposes, not his own but, of a third genericist, it is necessary, in that 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 relationship of "commissioning," by virtue of which the manufacturer is approached by the generic third party "for an activity of study production and delivery in turn lawful insofar as ex ante inherent to the aforementioned purpose" and the manufacturer acts "only by reason of a request supported by a declared purpose suitable to exculpate its conduct expressly contemplated - as a limit of use - in the relevant negotiating regulation."

The activities exculpated by subparagraph (b) of Article 68 are those aimed at the submission of a marketing authorization for a drug, and this purpose must emerge, in the case where the activity is carried out not for its own but for a third party's registration purposes, ex ante and unequivocally.

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Outside of a request from the party, the production/offer of the product appears to be unrelated to the purpose of obtaining an "AIC," and the profit that the manufacturer derives from the sale of the same is the remuneration of an activity of study and production, offering and publicizing, that is, an activity of mere commercial exploitation of the principle patented by others, which took place without any coverage of the exculpatory.

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

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

True, the small generic manufacturer (and therefore not having its own operating facilities) interested in filing and being granted an "AIC" application for its own generic drug, in advance of the patent or "CCP" expiration, will have to take action in good time, even several years in advance by making the appropriate request to a third-party manufacturer that can study and then produce the active ingredient needed for registration purposes.

But the timelines associated with the production of an active ingredient that the generic manufacturer "with an in-house production facility" will face (including those required to obtain the various regulatory approvals) are the same as those faced by the third-party manufacturer contacted by the smaller generic manufacturer.

And, again from the functional-teleological perspective of the extensive interpretation (it is repeated, however favorable to the plaintiffs, as opposed to a literal interpretation), correctly, the territorial court held that 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 genericist, also that this registration purpose be indicated at the negotiation level as a limit of use, as a provision of the commitment to the use of the active ingredient according to the Bolar purposes, supported by the stipulation of the payment of a penalty in case of violation of the commitment.

These are minimal precautionary measures in order to avoid uses of the active ingredient not scriminated by the exception.

Computer-assisted translation of the judgment

Ultimately, in order for the Bolar exemption to apply even to those who produce the active ingredient protected by the patent not 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 these necessary conditions do not appear to have been proven by the appellants in the trial on the merits, with a finding of fact that cannot be reviewed in this court of law.

Next, as to the circumstance, noted in the two briefs filed by the plaintiffs, regarding the reformulation, in the proposed reform of European pharmaceutical legislation published by the European Commission on April 26, 2023, of the Bolar exemption at the 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 under the heading "Exemption to the protection of intellectual property rights", a reformulation of the Bolar exemption at the European level was proposed in the sense of writing off "any activity (including information and offer to third parties ("offer"), production ("manufacture"), sale and supply ("sale" and "supply")), whether put in place by the company directly involved in the testing activity, or if put in place by third party suppliers ("third party suppliers"), and in the latter case without any limitation or pre-condition." b) most recently, last April 10, the European Parliament approved the Commission's proposal for a Directive at first reading, confirming the list of planned activities to be included within the Bolar exemption, as well as the subjective extension to "third party suppliers."

And it is deduced how 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 legislature 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 market entry of generic medicines ... which are based on a reference medicinal product, to clarify its scope in order to ensure harmonized application in all member states, both in terms of beneficiaries and 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 market entry of all genericists, without any discrimination.

This Court observes, in this regard, that, apart from any relief on the clarity and unambiguity of the interpretation of the new provision in the sense desired by the plaintiffs (and not also in the sense of providing for the operativeness of the Bolar exemption only for those conducts put in place exclusively for the purpose of conducting clinical studies aimed at obtaining a marketing authorization), this 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 how the previous rules did not allow the extension of the Bolar exception without limits and conditions.

Therefore, the following principle of law must 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 forth in Legislative Decree No. 30 of February 10, 2005, the result of the transposition in Italy 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 testing activities of a drug covered by another's patent, aimed at obtaining an administrative authorization to market the drug, which is intended to operate after the expiration of another's patent, are allowed, is to facilitate the timely market entry of generic drugs so as not to prolong, in effect, the duration of the patent, allowing generic manufacturers to begin the administrative and trial activities prodromal to obtaining a MA, even while the reference patent remains in force, by introducing limits to the right of exclusivity; the Bolar exception or exemption can also be considered applicable to the activity of third parties who produce the active ingredient of the patented drug, for registration purposes not their own but of third-party generic manufacturers, not equipped to produce on their own, but intending to enter the market, upon the expiration of the exclusivity of the patent title; however, such a 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 genericist, that this registration purpose is also indicated at the negotiation level as a limitation of use, as a prediction of the commitment to the use of the active ingredient according to the Bolar purposes."

3. For all the above, the appeal should be dismissed. Costs, awarded as set forth in the operative part, shall be awarded on a first-come, first-served basis.

P.Q.M.

The Court dismisses the appeal; orders the appellants, jointly and severally, to reimburse the court costs of the present trial of legitimacy, awarded in the total amount of 8,000.00 euros, as compensation, plus 200.00 euros for disbursements, as well as

the flat-rate reimbursement of general expenses, in the amount of 15%, and legal accessories.

Pursuant to Article 13, paragraph 1-quater of Presidential Decree 115/2002, it acknowledges the recurrence of the procedural prerequisites for the applicants to pay the amount by way of unified contribution, equal to that due for the appeal, if due, pursuant to paragraph 1-bis of the same Article 13.

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

Filed in the Registry on July 5, 2024.

Notes to judgment:

The 'Bolar Clause' and limitations on patent exclusivity (Molteni Beatrice)

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