NEW INVENTIVE STEP REQUIREMENTS TO PHARMACEUTICAL INVENTIONS IN UKRAINE: WILL IT HELP TO PROTECT A BALANCE BETWEEN PUBLIC AND PRIVATE INTERESTS?

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New edition of Rules for drafting, submitting, and examining an application for an invention and an application for a utility model adopted in Ukraine has the potential to limit evergreening for pharmaceutical inventions. The article analyzes the content of new anti-evergreening provisions for polymorphs, stereoisomers, and prodrugs introduced by the Rules, comparing them with international recommendations, European Patent Office and other jurisdictions' approaches. While this development may be perceived as positive, language on 'new technical property' may serve as a backdoor for patenting low-quality inventions.

Key words: evergreening patents, TRIPS flexibilities, medicines, access in Ukraine

Introduction. While the martial law situation due to the full-scale Russian invasion of Ukraine is continuing, the affordability of health products remains a pressing issue for the population and for the government of Ukraine, considering the significant economic downfall caused by the war. Intellectual property poses a barrier for accessibility of important medical technologies; therefore, in search for a balance between private and public interests, scientists have proposed so-called TRIPS flexibilities — strategies in interpretation of the TRIPS Agreement aimed at ensuring access to medicines and other technologies needed in low- and

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middle-income countries that are members of the WTO. One of the TRIPS flexibilities is the strict application of patentability criteria by patent offices when examining pharmaceutical inventions claimed by the big pharma companies.

To harmonize sub legislation with restatement of the Law of Ukraine "On Protection of Rights on Inventions and Utility Models", on September 9, 2024, Ministry of Economy of Ukraine adopted new edition of Rules for drafting, submitting, and examining an application for an invention and an application for a utility model (hereinafter — 'Rules for Examination') [1], which has introduced several novelties to the assessment of inventive step for new forms of known substances, in particular for polymorphs, isomers and prodrugs that may have significant impact in the long-term perspective on quality of examination of pharmaceutical patents. At the same time, it is unclear whether such provisions have the potential to limit the evergreening practice for pharmaceutical patents and whether patent applicants will be able to find loopholes in these new requirements. As strict application of patentability criteria for decades has been successfully practiced in several countries of Global South to prevent unmerited monopolies on pharmaceutical patents, and nowadays there are developed approaches to ensuring high quality of examination of polymorphs, isomers and prodrugs [2], it appears prudent to compare these approaches with novelties of the Rules for Examination to identify any deficiencies in new rules that may enable development of normative proposals for further improvements.

Literature review. The theoretical basis for studying the problem of intellectual property rights in relation to medicines, including the practice of evergreening, was laid by the following Ukrainian and foreign researchers: I. Volynets, O. Gurgula, I. Demchenko, S. Petrenko, O. Ponomareva, V. Selivanenko, M. Trofymenko, O. Zhykharev, R. Yurkiv, T. Amin, G. Chaves, C. Correa, A. Ferroz, A. Kapczynski, B. Sampat, K. Shadlen, M. Vieira, and others. At the same time, various rules and practices of foreign patent offices aimed to limit the evergreening practice and, most importantly, the assessment of the impact of such rules on actual reduction of unmerited pharmaceutical patents granting and accessibility of relevant medicines for the population requires more research. Comparison of the Ukrainian legal framework addressing the evergreening problem with other countries' approaches merits further research as well.

The purpose of the study is to analyze the content of new provisions of the Rules for Examination, compare the proposed approach with international recommendations, European Patent Office (EPO) approach, rules of several jurisdictions that use strict approaches to patenting similar new forms of known substances; and assess the potential implications of these novel provisions for ensuring a balance between public and private interests in the context of access to medicines.

This article is limited in scope to small molecule drugs and will not consider biological drug patenting rules, as those comprise a different set of rules due to significant technological differences.

Results of the study. The first novelty provided by the Rules for Examination relates to the introduction of detailed rules regarding inventive step requirements to new forms of known medicines. In 2020 restatement of the Law of Ukraine "On Protection of Rights on Inventions and Utility Models"[3], in part 7 of Art. 7, it was stipulated that new forms of a medicinal product known from the prior art, including salts, esters, ethers, compositions, combinations and other derivatives, polymorphs, metabolites, pure forms, particle sizes, isomers, may be recognized as clearly arising from the prior art, if they do not differ significantly in efficacy. This provision, similar to Indian Patent Law Section 3(d) [4], aims at addressing evergreening of pharmaceutical patents, was further clarified in part 7 of Chapter 21 of Section IV the Rules for Examination which requires the patent applicant to provide preclinical or clinical studies data proving difference in efficacy of new form compared to known efficacy of medicinal product, and some other important provisions intro-

duced to strengthen the provision of the Law of Ukraine "On Protection of Rights on Inventions and Utility Models". This is potentially an important mechanism for limiting evergreening of pharmaceutical patents, as this form of abuse of the patent system relies heavily on patenting new forms of known compounds, like salts, polymorphs, esters, ethers, metabolites, etc. This provision was probably inspired by the Indian experience, where the local pharmaceutical industry and civil society were among the main advocates of the active practical application of Section 3(d) by the Indian patent office to keep the operating space as wide as possible from patent monopolies after 2005, when India became obliged to start granting patents on medicines. It remains to be seen how the Ukrainian NIPO will apply the part 7 of Art. 7 of the Law of Ukraine "On Protection of Rights on Inventions and Utility Models" in practice, given the quite mild modality of this provision wording in the Ukrainian patent law compared to a similar provision in the Indian Patent Act.

Secondly, the new Rules for Examination in paragraph 5 of part 7 of Chapter 21 of Section IV stipulate that new crystalline forms (polymorphs), solvates, in particular hydrates, of a biologically active compound without a new technical property are considered to lack inventive step.

Before that, Ukraine allowed patenting of polymorphs, which was confirmed by the large number of issued patents related to polymorphs of certain medicines according to the 2020 Evergreening of Patents Study in Ukraine [5, p. 54]. Until August 2020, polymorphs were not directly mentioned either in the legislation governing the protection of rights to inventions, nor in the Methodological Recommendations of Ukrpatent [6]. There was only one decision of the Appellate Board of the Ministry of Economy and Trade concerning the polymorph of sofosbuvir [7], which we will discuss below, but it was rather an exception to the general approach. Therefore, when considering claims aimed at protecting polymorphs that were indicated in applications for inventions filed before August 2020, one should have been guided by the general provisions relating to inventions in the field of chemistry.

Thus, the new approach suggested by the new Rules for Examination differs from what existed before and supposedly will raise the bar for the examination as it sets sort of a priori approach of non-inventiveness of such new forms of known substance, at the same time question remains whether requirement to prove existence of new technical property will be restrictive enough not to be used as backdoor for evergreening efforts. We will look into it in more detail after comparing this approach to patenting polymorphs with international recommendations and foreign practice.

The phenomenon of polymorphism is long known in chemistry and is widely used in patenting in the pharmaceutical sector [8].

While polymorph claims are accepted by patent offices in many countries [9, p. 11], UN-backed guidelines for examination of pharmaceutical patent applications and patentability guidelines of countries that actively use strict patentability criteria flexibility, like Argentina and India, suggest a diametrically opposite approach.

According to the Argentinean Guidelines for Examination of Patentability of Patent Applications for Pharmaceutical Inventions (hereinafter – 'Argentinean guidelines'): "Since claims relating to polymorphs are the result of the simple identification and/or characterization of a new crystalline form of a substance already disclosed in the prior art, even if they show pharmacokinetic differences or differences in stability with respect to solid forms (amorphous and/or crystalline) of the same substance already known, such claims are not acceptable. 2. Processes for obtaining polymorphs are routine experiments in the manufacture of drugs; they are not patentable, since it is obvious that the most pharmaceutically acceptable polymorph is being sought by conventional methods" [10, p. 1(iv)]. In Section 3(d) of the Indian Patents Act, polymorphs of a known substance are not considered inventions unless they lead to a significant increase in the known efficacy of that substance. A similar approach is supported by the Guidelines for the examination of pharmaceutical patents:

developing a public health perspective developed by ICTSD, WHO, UNCTAD (hereinafter – 'WHO guidelines'): "Polymorphism is an intrinsic property of matter in its solid state. Polymorphs are not created, but discovered. Patent offices should be aware of the possible unjustified extension of the term of protection resulting from the successive patenting of an active substance and its polymorphs, including hydrates/solvates. Processes for obtaining polymorphs may be patentable in some cases if they are novel and meet the requirements of inventive step" [9, p. 11]. The Guidelines for the Examination of Patent Applications relating to Pharmaceuticals: Examining Pharmaceutical Patents From a Public Health Perspective developed by United Nations Development Programme (hereinafter – 'UNDP guidelines') recommend that "patents for polymorphs should be refused on the grounds of lack of patentable invention or inventive step. This conclusion may be drawn even in cases where the document that is the basis for the analysis of the inventive step in relation to the specific claimed polymorph is not identified; obtaining a polymorph is a routine activity in pharmaceutical manufacturing, carried out by methods widely known to those skilled in the art" [2, p. 25]. Thus, in contrast to the approaches of the EPO and Ukrainian Rules for Examination, the WHO Guidelines, the UNDP Guidelines, the Argentinean Guidelines and the Indian Patent Law adhere to the approach of a priori non-compliance of polymorphs with patentability criteria.

In the EPO's practice, patenting of polymorphs was regularly allowed in view of the practice of the German Patent Office and the Federal Patent Court, where in the Kristallformen case it was stated that "products with the same chemical formula are not considered identical (and therefore new) if they differ in some reliable parameter" [11, p. 112]. Current approach according to the case law of EPO could be summarised as mere provision of a new polymorph does not meet inventive step requirement, unless the claimed polymorph had an unexpected property meaning that its selection was non-arbitrary [12, 9.9.5]. Interestingly, some new properties of polymorphs in EPO practice appear to be deemed a priori obvious, e.g., improved filterability and drying characteristics [13], higher solubility [14]. While improved (reduced) hygroscopicity and an improved chemical stability[15] [16], improved stability compared to other polymorphic forms seems to be perceived as 'unexpected' and thus conveys the non-obviousness to intentionally selected polymorphic form. Moreover, in recent cases, the EPO created a notion of balance of beneficial properties, which theoretically may combine those 'expected' properties into an 'unexpected' balance of properties [17].

According to paragraph 2 of the part 13 of the Chapter 4 Section II of the Rules for Examination, 'a technical property means an external manifestation of the material nature of a product in its interaction with another material object, i.e., a manifestation that has a material nature and is based solely on mechanical, physical, chemical, biological, etc. phenomena and effects'.

Technical properties identification plays an important role in assessment of inventive step, as under paragraph 1 of the part 13 of the Chapter 4 Section III of the Rules for Examination 'technical result' means the discovery of new technical properties or improvement of the characteristics of known technical properties of the object of the invention (utility model), which can be obtained during its implementation. 'Technical result' is a core notion in Ukrainian legislation used during inventive step assessment, and it is similar to the 'technical problem' notion in EPO guidelines.

For polymorphs, technical properties examples could be improved stability, higher temperature of melting, better solubility, intermediate stability, and at the same time improved industrial processability and improved purity in terms of reduced amounts of residual solvents and residual impurities, etc. [17]. It appears that it might not be that complicated for the patent applicant to provide comparative data of the claimed polymorph with other polymorphic forms or amorphous forms, trying to prove the existence of at least one 'new technical property'.

New Ukrainian approach to 'new technical property' appears to be quite similar to the unexpected property criterion for non-obviousness of polymorphs of EPO, though there are important differences. Firstly, the term 'unexpected' appears to be more rigorous standard than just 'new', as the patent applicant has to show that the relevant property was not expected. It could also be argued that any property of a polymorph that meets the novelty requirement will be deemed as 'new property' for such concrete polymorph of a certain substance. Secondly, in EPO practice there is already quite detailed approach developed that excludes some of the properties from being 'unexpected' (improved filterability and drying characteristics, higher solubility), while there is no established practice in Ukraine in this regard, which means that theoretically polymorph having improved filterability may be deemed patentable, as this property will be deemed as 'new'.

Thus, will it mean that this new requirement of the Ukrainian Rules for Examination will not be complicated to comply with for the patent applicants when using a polymorphic form for evergreening strategy purposes? Only future practice by the Ukrainian National Office for Intellectual Property and Innovations (UANIPIO) will provide a definitive answer. At the same time, when patent applicant is appealing to 'new technical property', while in opinion of patent examiner certain polymorph is quite obvious, it may be possible to resort to Article 7.7 of the Law of Ukraine 'On Protection of Inventions and Utility Models' and apply criterion of significantly improved efficacy or use criterion of cause-and-effect relationship between properties of polymorph and drugs therapeutic application stemming from Appellate Board of Ministry of Economy decision on sofosbuvir [7].

New Rules for Examination has also introduced a provision that states that new prodrugs, metabolites, in particular, simple and complex esters (ethers and esters), without a new technical property, do not have an inventive step. This provision sets a new requirement which is quite progressive and could be helpful to protect public interests against the evergreening strategy using prodrugs.

Drug metabolism is the biotransformation of a drug into other compounds called metabolites, which occurs mainly in the liver through the chemical action of enzymes. Metabolites are formed in vivo after administration of the drug [11]. Metabolites can be either pharmacologically inactive or active. Active metabolites can exhibit activity similar to that of the drug or different from it, or be toxic and exhibit various side effects [22]. An active metabolite contains the same functional group as its parent drug. An active metabolite retains most, if not all, of the properties of the original drug until its carbon structure is combined into larger structures or reduced to smaller structures [2, p. 41].

The metabolism of a drug usually reduces the concentration of the drug in the systemic circulation, which usually leads to a decrease or complete inhibition of the pharmacological action of the drug. The exception is prodrugs, where the metabolism results in the formation of an active form (metabolite) of the drug [18, p. 51].

Although these new rules set a higher bar, there is still room for improvement. For example, regarding metabolites and prodrugs, the WHO guidelines, UNDP guidelines, and Argentinean guidelines recommend that active metabolites should not be patented separately from the active ingredient from which they are derived (the prodrug) [9, p. 19]. In this case, separate claims for metabolites should be prohibited on the grounds that metabolites are not inventions (since they are produced by the organism, they are not the result of creative activity), are not new (according to the concept of inherent disclosure), and are obvious (their advantages do not result from inventive activity) [10, p. 41]. From which we can conclude that both the prodrug and the metabolite should be described in only one patent.

Second, the WHO guidelines recommend that if a separate patent for a prodrug is granted later, in such cases, the metabolite formula should be excluded from such a prodrug patent if the metabolite was previously known or not patentable. Also, the claims for prodrugs should be sufficiently supported by information provided in the specification. "In

addition, evidence may be required that the prodrug is inactive or less active than the compound to be released, that metabolism of the prodrug provides an effective level of the metabolite, and that this minimizes direct metabolism of the prodrug and the gradual inactivity of the drug" [9, p. 19]. The current Argentinean guidelines in paragraph viii virtually repeat these recommendations of the WHO guidelines [10].

Unlike the WHO and Argentinean guidelines, the UNDP Guidelines place greater emphasis on inventive step and clarify its application to prodrugs, stating that a claim for a prodrug will not normally meet the inventive step standard unless it can be shown that it overcomes the pharmaceutical or pharmacokinetic problems of the original drug in a non-obvious manner. Also, according to the UNDP guidelines, general claims for specific prodrugs should be prohibited, and when examining claims for prodrugs, it should be checked whether the previous patent on the active substance covered the prodrug [2, p. 40]. India has taken a less stringent approach than Argentina with respect to metabolites, allowing a test of substantial improvement in the therapeutic efficacy of the metabolite over the known substance, in the presence of which the metabolite is considered an invention. Thus, the Patents Act 1970 provides in Article 3(d) that it is not an invention: "the mere discovery of a new form of a known substance which does not result in an increase in the known efficacy of that substance… Explanation. For the purposes of this paragraph, metabolites… and other derivatives of a known substance shall be considered to be the same substance if they do not differ significantly in their properties as regards efficacy" [4]. It is significant that Article 3(d) does not expressly include prodrugs, and the Indian Guidelines do not specifically mention them in any way, so that at least they should be assessed according to the general rules. On the other hand, this Article includes the expression "other derivatives of a known substance", which in essence should cover prodrugs as a derivative form of a metabolite, provided that the metabolite was previously known, and this interpretation is supported by scholars [19] and the practice of the Intellectual Property Appellate Board of India [20]. Thus, both metabolites and prodrugs are treated in India as new forms of a known substance, which are not inventions unless a significant improvement in therapeutic efficacy is demonstrated.

Unlike the above-mentioned guidelines and jurisdictions, the EPO guidelines do not lay down specific rules for metabolites and prodrugs, and the EPO practice allows the patentability of metabolites and prodrugs [21, pp. 10-11]. In case a metabolite is known, to comply with the inventive step requirement, the applicant needs to show that prodrug design was not obvious, and it is better if such a prodrug shows a surprising technical effect compared to metabolite [21, p. 10]. In rare cases when a prodrug was patented first, unlike the US PTO and UK patent office approaches, at EPO, it will still be possible to patent the metabolite even in such a situation, as the EPO does not accept the argument that the previous disclosure of a prodrug inherently disclosed and anticipated the metabolite [21, p. 11].

As in Ukraine, until 2020, the situation was similar to the EPO approach; the legislation and internal methodological document [6] did not specify any special rules regarding metabolites and prodrugs. The 2024 rule in the Rules for Examination may change the situation for the better. Though similar concerns regarding the weakness of the 'new technical property' criterion as described above in relation to polymorphs will apply to patenting of prodrugs. As prodrugs could have such new technical properties as better pharmacokinetic properties, including absorption, distribution, metabolism, and excretion, optimizing dissolution rates and lipophilicity [22], increased aqueous solubility, improved targetability, prolonged duration of action [23], and can theoretically justify compliance with inventive step requirement under the 'new technical property' criterion.

The last novelty is related to the inventive step of stereoisomers. The new Rules for Examination stated that: 'New spatial isomers (stereoisomers), in particular enantiomers, diastereomers, as well as compositions (mixtures) of stereoisomers, in which the spatial structure of the molecule is changed and as a result biological and/or other

properties may be changed, as a rule, have an inventive step, since the properties of new stereoisomers or their compositions (mixtures) are not obvious to a specialist. At the same time, if a new stereoisomer or a new composition of stereoisomers has only increased biological activity compared to a known stereoisomer or a mixture of stereoisomers (for example, a racemate) without a new technical property, and for its preparation conventional methods from the prior art were used, such a stereoisomer (new composition of stereoisomers) does not have an inventive step. Similarly, if a new stereoisomer or a new composition of stereoisomers has a new technical property or shows a reduction or absence of a known negative technical property compared to a known stereoisomer or mixture of stereoisomers, which is due to the absence or reduction in the amount of another stereoisomer (for example, a reduction in the toxicity of an isolated stereoisomer relative to a known racemate because the new stereoisomer is not toxic, unlike the other).'

The wording of the third sentence of this paragraph lacks an ending to form a full sentence, thus requiring the reader to infer what the IP regulator meant. Though it is possible to infer that it means that in case a stereoisomer has a new technical property or shows a reduction or absence of a known negative technical property compared to a known stereoisomer or mixture of stereoisomers, it does have an inventive step.

Stereoisomers are compounds composed of the same atoms bonded in the same sequence but having different spatial orientations. The term stereoisomer includes diastereoisomers and enantiomers [24, p. 1]. Enantiomers are two molecules containing the same number of atoms of the same kind, being also each other's mirror images (like gloves for the right and left hands) [25, p. 104]. Mixtures of enantiomers in equal proportion are called racemates or racemic mixtures [2, p. 27]. Physical properties (e.g., melting points, solubilities) of the racemates may differ from those of the individual enantiomers. A significant number of medicines on the market are racemates [24, p. 2].

In terms of pharmacokinetics, pharmacodynamics, toxicity, protein binding, and other characteristics enantiomers in a racemate differ substantially. In many cases, one of the enantiomers is mostly responsible for a given pharmacological activity in certain medicines, while the other enantiomer may be inactive or even toxic [24, p. 2]. The pharmaceutical industry exploited this feature for evergreening purposes, by first patenting the racemic mixture and then using the active enantiomer to obtain additional patent protection [9, p. 16], though this strategy does not always work successfully, as some racemates showed better pharmacological activity than single isomers [26, p. 283].

According to Grubb, in EPO and UK optical isomers have novelty if not disclosed, but no inventive step unless surprising superior properties demonstrated compared to racemate (with exception of situation when racemate is known and one of optical isomers shows superior pharmacological activity compared to other isomer, which is to be expected and is deemed to be obvious to the person skilled in the art), or if it has use that racemate did not have, or no separation processes for enantiomers were known [27, p. 249].

WHO and UNDP guidelines recommend that patent offices not recognize the novelty of single enantiomers if the racemate is disclosed (as the racemate formula necessarily discloses the existence of enantiomers), and it is obvious to the person skilled in the art to search and isolate the active enantiomer. However, processes for obtaining enantiomers, if novel and not obvious, could be patentable according to these guidelines. Though difficulty in isolating and purifying an enantiomer is not per se an indicator of inventive activity. [2, p. 29], [9, p. 17] Compared to the UN agencies guidelines approach, the Ukrainian Rules for Examination treat the non-obviousness of the method of obtaining the isomers as such that confers inventiveness to the isomer, which is an incorrect approach in our opinion, as such a non-obvious method could be patented separately, while leaving the stereoisomer out from product patent protection.

As was mentioned above, enantiomers are just one type of spatial isomers; UNDP and WHO guidelines do not address the patentability of other types of stereoisomers, like diastereomers. Argentinean guidelines address both types of stereoisomers, by saying that when the racemic compound formula is disclosed, the novelty of enantiomers and diastereomers is lost as the racemate molecular formula reveals the existence of enantiomers and diastereomers comprising the racemate. The Argentinean guidelines go even further by saying enantiomers and diastereomers are not patentable in the described above case, even if the patent application describes different properties of those [10, paragraph 1(iii)]. Notably, the Ukrainian Rules for Examination have an opposite approach, treating the existence of new technical properties in stereoisomers as an indication of the presence of an inventive step, even if the racemate is known.

In India, Section 3(d) treats isomers as mere new forms of known substances that should be treated as not inventions, unless they demonstrate enhancement of the known therapeutic efficacy of that substance [4]. Thus, the Indian standard is quite high, and it appears that after complying with this requirement, such an isomer will need to undergo novelty and inventive step assessments.

In Ukraine, before 2020, there were no explicit provisions in legislation concerning isomers, and patents on isomers were granted [5]. The 2024 provisions on stereoisomers of the Rules for Examination appears to be close in spirit to EPO approach, and far less stringent than what is suggested by UN-backed guidelines, or used in Argentina and India, as individual enantiomers could differ from known racemates demonstrating various properties, for example in melting points, solubilities, heats of fusion [24, p. 1], thus giving room for presence of 'new technical properties'. There is a risk that the 'new technical property' criterion for stereoisomers could be interpreted as any new property of a single isomer confirmed by comparative tests compared to a racemate or inactive enantiomer, and thus can prove compliance with the inventive step requirement. This rule could be exploited by creative patent attorneys to ensure that a relevant low-quality patent application passes successfully the scrutiny of examination.

Conclusion

New Rules for Examination introduced a set of new provisions that could potentially increase the quality of pharmaceutical patent examination and reduce the number of evergreening patents being granted in Ukraine. While this development may be perceived as positive, wording on 'new technical property' that enables compliance with inventive step for polymorphs, prodrugs, metabolites, and stereoisomers of known substances may undermine the intended purposes of new provisions and serve as a backdoor for patenting low-quality inventions in the framework of the evergreening strategy used by big pharmaceutical companies.

As optical isomers appear to be more obvious than diastereomers, there should be a separate set of rules on the inventiveness of optical isomers, instead of stipulating the same inventive step requirements applicable to all stereoisomers, as is provided in the Rules for Examination.

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Нові вимоги щодо винахідницького рівня для фармацевтичних винаходів в Україні: чи допоможуть вони захистити баланс між суспільними та приватними інтересами?

9 вересня 2024 року Міністерство економіки України прийняло нову редакцію Правил складання, подання та проведення експертизи заявки на винахід та заявки на корисну модель, яка містить кілька нововведень до оцінки винахідницького рівня для нових форм відомих речовин, що може мати значний вплив у довгостроковій перспективі на якість експертизи фармацевтичних винаходів і може сприяти захисту суспільних інтересів щодо доступу до лікарських засобів.

Основна мета дослідження полягає в тому, щоб проаналізувати зміст цих нових положень, порівняти запропонований підхід з міжнародними рекомендаціями, підходом Європейського патентного відомства, підходами юрисдикцій, які використовують суворі підходи до патентування аналогічних нових форм відомих речовин; а

також оцінити потенційні наслідки для забезпечення балансу державних та приватних інтересів щодо доступу до лікарських засобів.

Низка новел щодо оцінки винахідницького рівня фармацевтичних винаходів має суттєвий потенціал для зменшення кількості так званих вічнозелених патентів в Україні. Зокрема, згідно нових правил поліморфи, проліки, метаболіти, та в деяких випадках стереоізомери вважаються апріорі такими, що не відповідають винахідницькому рівню. Такий підхід є досить прогресивним, хоча в деяких юрисдикціях існують іще більш прогресивні підходи до експертизи цих видів нових форм відомих речовин, зокрема, аж до часткового виключення цих об'єктів з під об'єктів, які поширюється правова охорона. Також, оскільки оптичні ізомери видаються більш очевидними, ніж діастереомери, має існувати окремий набір правил щодо винахідницького рівня оптичних ізомерів, замість того, щоб встановлювати однакові вимоги до винахідницького рівня, що застосовуються до всіх стереоізомерів, як це передбачено в Правилах експертизи.

Хоча ці зміни до Правил проведення експертизи можна сприймати позитивно з точки зору підвищення стандартів експертизи для певних видів фармацевтичних винаходів, формулювання про «нову технічну властивість», може підірвати ціль цих нововведень та слугувати лазівкою для патентування низькоякісних винаходів у рамках стратегії «вічного озеленення» патентів, що використовується великими фармацевтичними компаніями.

Ключові слова: вічнозелені патенти, гнучкі положення ТРІПС, лікарські засоби, доступ в Україні

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