Odessa National Medical University
International **Faculty**
Department organization and economics of pharmacy

Syllabus of the academic discipline

Patenting science

Volume	90 hours (lectures - 10 hours, practical training - 20 hours), independent work of students - 60 hours)/ 3 credits ECTS
Semester, year of study	5th / 3rd year of study
Days, time, place	According to the timetable Department Organization and Economics of pharmacy
Teacher (s)	Sen. Teacher Vyshnytska Iryna Volodymyrivna
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Consultations	Consultations are held on Tuesdays from 14:30 to 16:00 and Saturdays from 9:00 to 13:00 according to the approved schedule

COMMUNICATION

E-mail oef@onmedu.edu.ua; Microsoft Teams, Zoom; messengers: Viber, Telegram, WhatsApp

COURSE ANNOTATION

The subject of the discipline

The subject of the study of the regulatory discipline is information about the rights and benefits of authors of inventions, utility models, industrial designs, marks for goods and services, the content of patent documentation, the conditions for conducting patent research, the preparation of a patent form and the use of patent information.

Pre-requisites and post-requisites of the course:

"Patenting science" as an academic discipline: introduces general issues of innovation, inventive, patent and rationalization activities, the basics of Ukrainian legislation on intellectual property and protection of rights to inventions, utility models, trade marks.

It is based on the study by students of the introduction to pharmacy, pharmaceutical law and legislation, the basics of economics, higher mathematics, as well as professionally oriented disciplines - pharmacology, pharmaceutical chemistry, drug technology, provides for the integration of teaching with these disciplines and the formation of skills to apply knowledge of patent science in the process of further education and in professional activities.

Purpose of the course:

is to master the necessary knowledge in inventive and patent-licensing activities, methodological foundations for the creation of industrial property objects and engineering psychology, protection of patent rights, patent information systems; the ability to use in practice normative legal acts while ensuring the legal protection of scientific and technological achievements and creative products, to conduct patent information research in a particular field of technology, to find analogues and file an application for an industrial property object.

Objectives of the course:

studying the theoretical foundations and obtaining practical skills in the management of industrial property objects; increasing the efficiency of the functioning of innovative enterprises, government agencies and other objects of innovative infrastructure.

Expected results:

Program learning outcomes for the discipline:

PLO 1. To carry out professional activities in social interaction based on humanistic and moral principles; identify future professional activities as socially significant for human health.

PLO 2. Apply knowledge of general and special disciplines in professional activities.

PLO 4. Demonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex specialized tasks of professional activity.

PLO 6. Argue information for making decisions, be responsible for them in standard and non-standard professional situations; adhere to the principles of deontology and ethics in professional activities.

PLO 7. Perform professional activities with creative methods and approaches.

PLO 8. Carry out professional communication in the state language, use the skills of oral communication in a foreign language, analyzing texts of a professional orientation and translate foreign language sources of information.

PLO 9. Carry out professional activities with the use of information technology, "Information databases", navigation systems, Internet resources, software and other information and communication technologies.

PLO 24. Plan and implement professional activities on the basis of regulations of Ukraine and recommendations of good pharmaceutical practices.

PLO 29. Ensure a competitive position and effective development of pharmaceutical organizations on the basis of research work that is carried out on all elements of the marketing mix.

COURSE DESCRIPTION

Forms and methods of teaching

The training course consists of lectures (10 hours) and practical classes (20 hours), independent work of students (60 hours).

Problem-based presentation, case studies, discussions, work in a computer class (moodle-testing), electronic (review or problem) lectures, presentations, "business games" are used as teaching methods

Content of the discipline

Topic 1. General concepts of law and its system. Concept, subject and principles of patent law.

Topic 2. The system of sources of patent law and its relationship with civil, administrative, economic and criminal law.

Topic 3. Objects and subjects of patent law.

Topic 4. Protection of rights to industrial property.

Topic 5. Legal regulation of means of individualization of participants in civil circulation, goods and services.

Topic 6. Trade secret.

Topic 7. Licensing agreements for industrial property objects.

Topic 8. Registration of patent rights in foreign countries.

LIST OF RECOMMENDED LITERATURE

Basic:

1. Jae Sundaram. Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines. Routledge. 2018. 256 p.

2. Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective/ Edited by Josef Drexl, Director, Max Planck Institute for Innovation and Competition, Munich, Germany and Nari Lee, Hanken School of Economics, Helsinki, Finland. 2015. 352 pp

additional literature

1. Ahn, Hyewon. Second Generation Patents in Pharmaceutical Innovation. 1st ed., Nomos Verlagsgesellschaft MbH, 2014. JSTOR, www.jstor.org/stable/j.ctv941t5f. Accessed 2 Aug. 2021.

2. Monica Donghi. Patent Strategy in Pharmaceutical Industry: Are additional patents valuable? (Munich Intellectual Property Law Center - MIPLC). Nomos Publishers. 2014. 84 p.

3. Patenting: textbook and workshop for undergraduate, specialist and graduate programs / E. A. Sosnin, V. F. Kaner. M.: Yurayt Publishing House, 2019.384 p.

5. Implementation of Standards of Good Pharmacy Practice in the World: A Review / Liana Unhurian, Oksana Bielyaieva, Irina Vyshnytska, Natalia Suschuk, Irina Petkova // Asian Journal of Pharmaceutics. Jan-Mar 2018 (Suppl). 12 (1). - R. 42-46.

6. Justine Pila and Paul Torremans. European Intellectual Property Law: Second Edition, 2019.712 p.

7. Tanya Aplin and Jennifer Davis. Intellectual Property Law: Text, Cases, and Materials, Fourth Edition, 2020. 952 p.

Informational resources

1. State Enterprise "Ukrainian Institute of Intellectual Property" (Ukrpatent). URL: https://ukrpatent.org/uk

2. Department of Patent Information Services, Consulting and Promotion of Innovation Activities of the State Enterprise "Ukrainian Institute of Intellectual Property". URL: http://iii.ua/

3. The Constitution of Ukraine: adopted at the fifth session of the Verkhovna Rada of Ukraine on June 28, 1996 (as amended) [Electronic resource]. URL: http://zakon2.rada.gov.ua/laws/show/254k/96-vr.

4. Research Institute of Intellectual Property. URL: http://ndiiv.org.ua/index.php/
5. Civil Code of Ukraine (as amended) [Electronic resource]. - Access mode: http://zakon.rada.gov.ua/
6. Abstracts ETDE Word Energy Base. URL: https://www.etde.org/edb/energy.html
7. Springer journals. URL: https://www.springer.com/la/
8. IEEE Computer Society Electronic Library URL: https://www.computer.org/
9. FDA [E-resource]. - Access: https://www.fda.gov
10. Personal Data in Competition, Consumer Protection and Intellectual Property Law: Towards a Holistic Approach? / Mor Bakhoum, Beatriz Conde Gallego, Mark-Oliver Mackenrodt, Gintarė Surblytė-Namavičienė: MPI Studies on Intellectual Property and Competition Law, 2018 (eBook). URL: https://doi.org/10.1007/978-3-662-57646-5
11. WHO [E-resource]. - Access: https://www.who.int

EVALUATION

There are various forms of control for classes (oral, written, combined, testing, practical skills, etc.). The results of the academic progress for students exhibited in the form of evaluation on a national scale, 200-point scale, ECTS and have standardized, generalized assessment criteria:

Criteria for assessing the student's current learning activity

- the mark "excellent" ("5") is given to a student who has systematically worked, has shown versatile and deep knowledge of the program material, is able to successfully complete the tasks provided by the program, has mastered the content of the main and additional literature, realized the relationship of individual sections of the discipline, their importance for the future profession, showed creative abilities in understanding and using educational and program material, showed the ability to independently update and replenish knowledge; the level of competence is high (creative);
- the mark "good" ("4") is given to a student who has shown complete knowledge of the educational and program material, successfully fulfills the tasks provided by the program, has mastered the basic literature recommended by the program, has shown a sufficient level of knowledge in the discipline and is capable of independently replenishing and updating them in the course of further education and professional activities; the level of competence is sufficient (constructive and variable);
- the mark "satisfactory" ("3") is given to a student who has shown knowledge of the basic educational and program material in the amount necessary for further study and subsequent work in the profession, copes with the tasks provided by the program, made some mistakes in answers, but has the necessary knowledge to overcome the mistakes made under the guidance of a scientific and pedagogical worker; competence level - average (reproductive);
- the mark "unsatisfactory" ("2") is given to a student who did not reveal sufficient knowledge of the basic educational and program material, made fundamental mistakes in performing the tasks provided for in the program, cannot use knowledge in further training without the help of a teacher, and could not master the skills of independent work; the level of competence is low (receptive-productive).

The procedure for assessing the student's educational activity:

- assessment of current academic performance of the discipline

Current academic performance of the discipline's topics is evaluated according to the traditional 4-point scale. In a practical lesson, students should be interviewed at least once every 2-3 practical lessons (no more than 75% of students). At the end of the semester, the average number of students' grades in a group should be the same.

At the end of the study of the discipline, the current performance is calculated - the average current score (the arithmetic mean of all current grades on the traditional scale, rounded to two decimal places). To increase the average score in the discipline, the current marks "3" or "4" are not re-evaluated.

- assessment of independent work of students

The task of independent work of students is to obtain additional information for a more in-depth study of the discipline in practical classes. Independent work of students, which is provided by the topic of the lesson is assessed during the current control of the topic in the corresponding lesson.

- final control of knowledge by discipline

The final control in the form of final test is assessed on a two-point scale:

- the mark "passed" is given to a student who has completed the curriculum of the discipline and has no academic debt; , their average grade of current performance is 3.00 or more, in the last lesson they receive a test, which is set as "passed"; the level of competence is high (creative);
- the mark "not passed" is given to a student who has not completed the curriculum of the discipline, has academic debt (average score below 3.0 and / or missing classes), the level of competence is low (receptive-productive).

Conversion of the traditional national assessment into a multi-point one (maximum 200 points) is required. If a student receives a minimum grade point average of 3.00 in current performance, even if there are unsatisfactory grades that have not been completed, he / she receives a discipline test.

Converting Traditional Discipline Assessment
on a multi-point scale

A multi-point scale characterizes the actual progress of each student in mastering the academic discipline. The conversion of the traditional grade in the discipline into a 200-point grade is carried out by the information and computing center of the university by the "Contingent" program according to the formula:

grade point average (current / by discipline) x 40

National Assessment	Points
"5"	185-200
"4"	151-184
"3"	120-150

on the ECTS scale

The ECTS rating scale evaluates the achievements of students in the discipline who study in one course of one specialty, according to the points they received, by ranking, namely:

ECTS score	Statistical indicator
"A"	top 10% of students
"B"	next 25% of students
"C"	next 30% of students
"D"	next 25% of students
"E"	the remaining 10% of students

The ECTS scale establishes the student's belonging to the group of the best or worst among the reference group of fellow students (faculty, specialty), that is his rating. When converting from a multi-point scale, as a rule, the boundaries of grades "A", "B", "C", "D", "E" do not coincide with the boundaries of grades "5", "4", "3" on the traditional scale. The "A" grade on the ECTS scale cannot be equal to the "excellent" grade, and the "B" grade - the "good" grade, etc.

Students who have received grades "FX" and "F" ("2") are not included in the list of ranking students. Such students, after retaking, automatically receive an "E" score.

The mark "FX" is given to students who have scored the minimum number of points for the current educational activity, but who are not credited with the final control. Grade "F" is given to students, attended all classroom lessons in the discipline, but did not score an average score (3.00) for the current educational activity and were not admitted to the final control.

COURSE POLICY

Deadline and retake policy

Students for education are expected to attend all lectures and practical classes. If they missed classes, it is necessary to make-up them (according to the schedule posted on the information stand of the department and according to the permission of the dean's office, if necessary).

The retake of the control of the acquisition of practical skills is carried out during the semester on an individual basis with the determination of the time of the training.

Retake of unsatisfactory grades is carried out during the term of studying the discipline, provided that the average score for the current educational activity is less than 3.00 (carried out according to the schedule posted on the information stand of the department).

Academic Virtue Policy

Respect for academic virtue by education seekers includes:

- independent fulfillment of educational tasks, tasks of current and final control (current controls and discipline exam) of learning outcomes (for persons with special educational needs, this requirement is applied taking into account their individual needs and capabilities);

- links to sources of information when using ideas, developments, statements, information;

- provision of reliable information about the results of their own (scientific, creative) activities, the research methods used and sources of information.

It is unacceptable in educational activities for participants in the educational process to use prohibited auxiliary materials or technical means (crib notes, earpieces, phones, smartphones, tablets, etc.) during control events.

For violation of academic virtue, education seekers may be held liable for such academic responsibility

• decrease in the results of assessment (control work, exam);

• re-passing the assessment (test, exam);

• appointment of additional control measures (additional individual tasks, control works, tests, etc.).

Attendance policy

Attendance at lectures and practical classes is compulsory. If you are more than 15 minutes late, the lesson is considered missed and requires working out.

Mobile devices

During practical exercises, the use of a smartphone, tablet or other device for storing and processing information is allowed only with the permission of the tutor.

When conducting any form of control, the use of mobile devices and their accessories is strictly prohibited.

Audience behavior

During the classes it is allowed: to leave the audience for a short time, if necessary and with the permission of the teacher; photograph presentation slides; actively participate in the class.

During the lessons it is prohibited: to eat (except for persons whose special medical condition requires another - in this case, medical confirmation is required), smoking, drinking alcoholic and low-alcohol drinks or drugs; use obscene language or use words that offend the honor and dignity of colleagues and faculty; gamble; damage the material and technical base of the university (spoil inventory, equipment; furniture, walls, floors, litter premises and territories), make noise, shout or listen to loud music in classrooms and even in the corridors during classes.