

**Danylo Halytsky Lviv National Medical University**  
**Department of Pharmaceutical, Organic and Bioorganic chemistry**

**APPROVED**

First pro-rector  
for the Academic Work  
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**SYLLABUS FOR**  
**“Fundamentals of**  
**patent”**

**Second (master's) educational level**  
**Field 22 «Health»**  
**Specialty 226 «Pharmacy»**

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prof. R.B. Lesyk

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## **1. DESCRIPTION OF THE COURSE**

Nowadays, the role of science in solving fundamental problems of accelerating socio-economic development of Ukraine is growing significantly. First of all, the task is to strengthen the material and technical base of science, to create the right conditions for the fruitful work of scientists. That is why the Constitution of Ukraine proclaimed the free development of the individual (Article 23), the freedom of scientific and technical creativity is guaranteed to the citizens of Ukraine (Article 54).

Works of science become an asset to society, the general public, when they are widely distributed, that is, released into the world in the form and order determined by the current legislation.

Publications and other methods of reproduction of works of science are carried out by special organizations - publishing houses, television, radio broadcasting. Relations between authors and these organizations formulate patents as the most perfect legal form enabling the author to exercise his rights and interests properly. The author has the opportunity in the contract to best protect his interests and rights, including the relevant terms and conditions.

The fundamental rights of the author, such as the right to publish or publish, the right to reproduce, the right to distribute, can only be realized through such legal document as the contract. An important condition is not only the recognition of the authors, but also the safeguarding of these rights.

Authors of rights should be able to take action against persons who violate their rights, compensate for damages, moral and material. Thus, the patent owner's rights protection system must be backed up by an effective rights protection system, must have a legal framework and infrastructure, staffed with the requisite number of specialists with appropriate training and experience.

Patent Program for Pharmaceutical Institutions of Education of Ukraine III-IV accreditation levels compiled for the specialty 7.12020101 "Pharmacy" compiled in accordance with the educational and qualification characteristics (OKH) and educational and professional programs (OPP) training of specialists of educational qualification level

"specialist", approved by the order of the Ministry of Education and Science of Ukraine №239 of 16.04.03, an experimental curriculum developed on the principles of the European Credit Transfer System (ECTS).

The term of study in the specialty "Pharmacy" is carried out for 5 years. According to the syllabus, the study of patent science is carried out in the 9th semester (specialist).

Patent science as a discipline is based on the study of students of pharmaceutical law, organization and economics of pharmacy, technology of drugs, pharmaceutical chemistry, clinical pharmacy and integrate with these disciplines.

For students of pharmaceutical universities and pharmaceutical faculties, patent science is one of the disciplines used to master the knowledge of innovation and investment activities of pharmaceutical and chemical-pharmaceutical enterprises and practical skills in patent processing.

Types of training according to the curriculum are: a) lectures; b) laboratory work; c) independent work of students; d) consultation.

The assimilation of the topic (current control) is monitored in laboratory classes according to specific goals; mastering content modules (intermediate control) - in laboratory classes using theoretical questions, computer tests, solving situational problems, passing practical skills.

The final control is carried out at the final control session. Assessment of student achievement in the discipline is a rating and is ranked on a multidimensional scale, taking into account the results of semester control and certification of students.

**Description of the curriculum in the discipline " Fundamentals of  
patent"**

**for students of the Faculty of Pharmacy  
specialty 7.12020101 "Pharmacy"**

Structure of the discipline	Number of credits, hours, of them				Year of study	Type of control
	Total Credit hours	Auditorium		Self-study		
		Lectures	Practical classes			
<b>Module: Fundamentals of patent Content Modules 2</b>	<b>1,0 credits ECTS / 30 hours</b>	<b>16</b>	<b>4</b>	<b>10</b>	<b>5 (IX semester)</b>	<b>credit</b>
<b>semester</b>						
<i>Content Modules 1-2</i>	<b>1,0 credits ECTS / 30 hours</b>	<b>16</b>	<b>4</b>	<b>10</b>	<b>IX semester</b>	<b>credit</b>

Auditory work – 66,7%; Self-study – 33,3%.

## 2. AIM AND OBJECTIVES OF THE EDUCATIONAL DISCIPLINE

The purpose of patent science as a subject of study is to train specialists who possess the theoretical background and practical skills in the legal bases of acquisition, transfer, protection and protection of intellectual property rights, in particular, industrial property in Ukraine and in the world. The curriculum provides knowledge of the basic principles of legal regulation of relations between the parties related to patenting in medicine and pharmacy, mastering the practical skills of patent rights, as well as materials on their legal protection and transfer of property rights to objects of intellectual property rights.

In the course of studying the discipline " Fundamentals of patent" students should:

to get acquainted with the current regulatory framework of Ukraine;

To learn the basic concepts and terms of regulatory documents;

Learn to be guided in the procedure of patent ownership (priority of ownership);

be able to protect patent property.

The essence of teaching discipline is to study the provisions of the legal framework of documentation on inventions and rationalization and the system of the legal side of intellectual property. The main tasks are:

familiarization and mastering of the main provisions of legislative and regulatory inventions, documents concerning developments;

familiarization with the procedure of keeping documentation on patent property in Ukraine

familiarization with the system of protection of rights to patent property objects, rules and rules for ensuring protection of rights to patent property in Ukraine

familiarization with the international practice of cooperation of Ukraine in the field of patent rights protection.

### **3. ПРОГРАМА НАВЧАЛЬНОЇ ДИСЦИПЛІНИ**

#### **Content module 1. Main provisions of the intellectual property regulatory framework**

Specific goals:

Analyze the legal framework governing the protection of intellectual property in Ukraine and the world.

To study the structure of governing bodies in the field of intellectual property.

To learn to identify industrial property in the field of medicine and pharmacy.

Analyze inventions and utility models as patentable objects.

#### **Theme 1. Conceptual principles of innovation and investment development of the pharmaceutical industry**

#### **Topic 2. Legal protection of medicines in Ukraine and in the world. Copyright and related rights**

#### **Theme 3. General characteristics of industrial property. Special legislation of Ukraine in the field of industrial property**

#### **Content module 2. Patenting as the primary form of industrial property protection**

Specific goals:

Explain the patenting procedure in Ukraine.

To file for a patent.

Be able to conduct patent research using Databases, Information and Reference System (CID) of the State Enterprise "Ukrainian Institute of Industrial Property".

Analyze the terms and procedure for the transfer of industrial property rights by means of licensing agreements.

To forecast the development of new technologies.

#### **Topic 4. Procedure for obtaining patents for inventions and utility models**

#### **Topic 5. Patent research. The role of industrial property information and documentation in pharmacy. Examination of the industrial property right application**

#### **Topic 6. Licensing and Transfer of Property Rights to Inventions, Utility Models and Other Intellectual Property Rights**

#### **Topic 7. International Patent Law**

#### **Topic 8. Economics of Intellectual Property**

#### 4. СТРУКТУРА НАВЧАЛЬНОЇ ДИСЦИПЛІНИ

№	Theme	Lectures	Practical classes	Self-study	Individual work
<b><i>Content module 1. Basic provisions intellectual property regulatory framework</i></b>					
<b>1</b>	Conceptual principles of innovation and investment development of the pharmaceutical industry	<b>2</b>	-	<b>2</b>	
<b>2</b>	Legal protection of medicines in Ukraine and in the world. Copyright and related rights	<b>2</b>	<b>1</b>	<b>1</b>	
<b>3</b>	General characteristics of industrial property. Special legislation of Ukraine in the field of industrial property	<b>2</b>	<b>1</b>	<b>1</b>	
<b><i>Together for Content Module 1</i></b>		<b>6</b>	<b>2</b>	<b>4</b>	
<b><i>Content module 2. Patenting as the main form protection of industrial property</i></b>					
<b>4</b>	The procedure for obtaining patents for inventions and utility models	<b>2</b>	-	<b>1</b>	
<b>5</b>	Patent research. The role of industrial property information and documentation in pharmacy. Examination of the industrial property right application	<b>2</b>	<b>1</b>	<b>1</b>	
<b>6</b>	Licensing and transfer of property rights to inventions, utility models and other intellectual property objects	<b>2</b>	<b>1</b>	<b>2</b>	
<b>7</b>	International Patent Law	<b>2</b>	-	<b>1</b>	
<b>8</b>	Economics of Intellectual Property	<b>2</b>	-	<b>1</b>	
<b>Together for content module 2</b>		<b>10</b>	<b>2</b>	<b>6</b>	
<b>Total hours 30 / 1,0 ECTS credits</b>		<b>16</b>	<b>4</b>	<b>10</b>	
<b>Final control</b>					<b>Credit</b>

Auditory work – 66,7 %, Self-study – 33,3 %.



## 5. TOPICS OF LECTURES

### THEMATIC PLAN OF LECTURES ON THE DISCIPLINE " FUNDAMENTALS OF PATENT"

№	The topic of the lecture	Hours
	Content module 1. Basic provisions	
<b>1</b>	intellectual property regulatory framework	<b>2</b>
<b>2</b>	Conceptual principles of innovation and investment development of the pharmaceutical industry.	<b>2</b>
<b>3</b>	Legal protection of medicines in Ukraine and in the world. Copyright and related rights.	<b>2</b>
	General characteristics of industrial property. Special legislation of Ukraine in the field of industrial property.	<b>6</b>
	<b>TOGETHER</b>	
<b>4</b>	Content module 2. Patenting as the main form	<b>2</b>
<b>5</b>	protection of industrial property	<b>2</b>
<b>6</b>	Procedure for obtaining patents for inventions and utility models.	<b>2</b>
<b>7</b>	Patent research. The role of industrial property information and documentation in pharmacy. Examination of the industrial property right application.	<b>2</b>
<b>8</b>	Licensing and transfer of property rights to inventions, utility models and other intellectual property rights.	<b>2</b>
	International Patent Law.	<b>10</b>
	Economics of Intellectual Property.	<b>16</b>

## 6. LABORATORY TOPICS

### THEMATIC PLAN OF LABORATORY CLASSES IN THE DISCIPLINE "FUNDAMENTALS OF PATENT"

<b>№</b>	The topic of laboratory work	<b>Hours</b>
	Content module 1. Basic provisions	
<b>1</b>	intellectual property regulatory framework	<b>2</b>
	Legal protection of medicines in Ukraine and in the world. Copyright and related rights. General characteristics of industrial property. Special legislation of Ukraine in the field of industrial property.	<b>2</b>
	<b>TOGETHER</b>	
<b>2</b>	Content module 2. Patenting as the main form	<b>2</b>
	protection of industrial property	<b>2</b>
	Patent research. The role of industrial property information and documentation in pharmacy. Examination of the industrial property right application. Licensing and transfer of property rights to inventions, utility models and other intellectual property rights.	<b>4</b>

## 7. INDIVIDUAL WORK

### THEMATIC PLAN OF INDEPENDENT WORK IN THE DISCIPLINE "FUNDAMENTALS OF PATENT"

<b>№</b>	<b>Independent work theme</b>	<b>Hours</b>
	Content module 1. Basic provisions	
<b>1</b>	intellectual property regulatory framework	<b>2</b>
<b>2</b>	Conceptual principles of innovation and investment development of the pharmaceutical industry.	<b>1</b>
<b>3</b>	Legal protection of medicines in Ukraine and in the world. Copyright and related rights.	<b>1</b>
	General characteristics of industrial property. Special legislation of Ukraine in the field of industrial property.	<b>4</b>
	<b>TOGETHER</b>	
<b>4</b>	Content module 2. Patenting as the main form	<b>1</b>
<b>5</b>	protection of industrial property	<b>1</b>
<b>6</b>	Procedure for obtaining patents for inventions and utility models.	<b>2</b>
<b>7</b>	Patent research. The role of industrial property information and documentation in pharmacy. Examination of the industrial property right application.	<b>1</b>
<b>8</b>	Licensing and transfer of property rights to inventions, utility models and other intellectual property rights.	<b>1</b>
	International Patent Law.	<b>6</b>
	Economics of Intellectual Property.	<b>10</b>

## **8. TEACHING METHODS**

The main methods of study in the study of the discipline "Fundamentals of patent" are lectures and practical classes.

The main theoretical material of the discipline is given while lecturing. The objective of the lecture material is to study the provisions of the legal framework of documentation on inventions and rationalization and the system of the legal side of intellectual property, familiarization with the system of protection of rights to patent property, rules and rules to ensure the protection of rights to patent property in Ukraine and international practice of cooperation of Ukraine in the field of patent rights protection.

In practical classes, students learn to use the necessary regulatory and technical documentation, to draw up documentation (application) for a patent to draw up the necessary documentation for the protection of rights in administrative or judicial order. Teachers study the discipline, mastering theoretical material and practical skills using A-format tests and oral examination. Test questions and situational tasks are made on the basis of the material indicated in the content of the topic and given in the methodological recommendations for each lesson.

## 9. CONTROL METHODS

The main methods of control in the study of the discipline " Fundamentals of patent" are current control and final semester control in the form of credit.

Ongoing monitoring is carried out at each lab session according to the specific objectives of the topic. All laboratory work uses objective control of theoretical training and practical skills.

At each practical session the student answers the test tasks, questions on the topic of the practical lesson, knowledge of which is necessary for understanding the current topic, questions of the lecture course and independent work related to the current lesson, demonstrates the knowledge and skills of practical skills in accordance with the topic of the laboratory lesson.

Independent work of students is evaluated during the ongoing control of the topic in the relevant lesson. The assimilation of topics that are presented only for independent work, is controlled by the final control.

The final control is conducted in order to evaluate the learning outcomes at a particular educational qualification level and at some of its completed stages on a national and ECTS scale. Final control includes semester control and student certification.

Semester control in the discipline " Fundamentals of patent" is conducted in the form of credit at the end of the 9th semester in the amount of study material defined by the work program in the discipline and in terms set by the work curriculum or the individual curriculum of the student.

Semester credit is a form of final control that consists in assessing the student's learning of a course material from a particular discipline solely on the basis of the results of the completion of all types of educational work provided by the work curriculum. The semester credit is set according to the results of the current control.

## 10. DISTRIBUTION OF STUDIES RECEIVED BY STUDENTS

The maximum number of points that a student can gain in studying the discipline for the current academic activity for the semester, the form of final control at the end of which is credit, is 200 points.

The minimum number of points that a student must earn for his / her current academic activity to enroll in the discipline is 120 points.

The calculation of the number of points is made on the basis of the student's scores on the traditional scale during the study of the discipline during the semester, by calculating the arithmetic mean (CA), rounded to two decimal places. The resulting value is converted to scores on a multicolor scale as follows:

$$x = \frac{CA \times 200}{5}$$

**Table 1**

4-point rate	200-point rate	4-point rate	200-point rate	4-point rate	200-point rate	4-point rate	200-point rate
5	200	4.47	179	3.94	158	3.42	137
4.97	199	4.45	178	3.92	157	3.4	136
4.95	198	4.42	177	3.89	156	3.37	135
4.92	197	4.4	176	3.87	155	3.35	134
4.9	196	4.37	175	3.84	154	3.32	133
4.87	195	4.35	174	3.82	153	3.3	132
4.85	194	4.32	173	3.79	152	3.27	131
4.82	193	4.3	172	3.77	151	3.25	130
4.8	192	4.27	171	3.74	150	3.22	129
4.77	191	4.24	170	3.72	149	3.2	128
4.75	190	4.22	169	3.7	148	3.17	127
4.72	189	4.19	168	3.67	147	3.15	126
4.7	188	4.17	167	3.65	146	3.12	125
4.67	187	4.14	166	3.62	145	3.1	124
4.65	186	4.12	165	3.6	144	3.07	123
4.62	185	4.09	164	3.57	143	3.05	122
4.6	184	4.07	163	3.55	142	3.02	121
4.57	183	4.04	162	3.52	141	3	120
4.55	182	4.02	161	3.5	140		
4.52	181	3.99	160	3.47	139		
4.5	180	3.97	159	3.45	138		
						Less than 3	Insufficient

### Determination of the number of points scored by the student from the discipline

Assessment of the discipline for the semester, the form of final control of which is the credit, is based on the results of current educational activities and is expressed on a two-point scale "enrolled" or "unaccounted for". For enrollment, the student must receive a grade of not less than 60% of the total amount of credits from the discipline according to Table 1 (120 points) for the current academic activity.

Discipline points are independently converted to both the ETCS scale and the 4-point scale. ETCS points are not converted to 4-point scale and vice versa.

The points of students studying in one specialty, based on the number of points earned from the discipline, are ranked on the ETCS scale as follows:

<b>ECTS Mark</b>	<b>Statistical index</b>
A	Top 10% of students
B	The next 25% are students
C	The next 30% are students
D	The next 25% are students
E	The last 10% are students

Discipline points for students who have successfully completed the program are converted to the traditional 4-point scale by the absolute criteria given in the table below:

<b>Points from discipline</b>	<b>Mark by 4-point rate</b>
From 170 to 200 points	5
From 140 to 169 points	4
From 139 to the minimum number of points which student must get	3
Below the minimum number of points which student must get	2

ECTS scores are not converted to the traditional scale because the ECTS scale and the four-point scale are independent.

## 11. METHODOICAL SUPPLY

№	Guidelines
1	Methodical instructions for laboratory work and independent work for students of the 5th year of the Faculty of Pharmacy «Стандартизація лікарських засобів» / Владзімірська О.В., Лесик Р.Б., Дасюк Є.В. та ін. – Львів – 2010. – 120 с.



## **12. LIST OF QUESTIONS TO BE MADE TOTAL CONTROL**

### **The list of questions for the credit in the discipline " Fundamentals of patent"**

1. The essence and features of innovation-investment processes in pharmacy.
2. The current state and tendencies of development of innovation-investment processes in pharmacy.
3. Objects and subjects of intellectual property rights, their classification and characteristics.
4. Legislative framework of intellectual property. Organizational structures of intellectual and property protection.
5. The need for legal protection of medicines. Types of Intellectual Property in the Pharmaceutical Industry.
6. Systems for the acquisition of rights to medicinal products and their characteristics. Patentability criteria for "pharmaceutical" inventions.
7. Structure of the State Intellectual Property Protection System.
8. International intellectual property system. World Intellectual Property Organization (WIPO).
9. General concepts of patent law and its system. Basic concepts, subject matter and principles of patent law.
10. System of sources of patent law. Relation of patent rights to civil, administrative, commercial and criminal law.
11. Objects and subjects of patent law. The concept, criteria and features of the invention (utility model). Legal protection conditions.

12. Rules for making an application for an invention (utility model), setting a technical task. Requirements for the description, formula and abstract of the invention.
13. Legal protection of patent law objects.
14. The concept of patent information and documentation, the characteristics of components and their functions.
15. Types of Patent Information Sources of patent information.
16. Patent information activity, its legislative and regulatory framework. Patent information bodies, their main functions.
17. Patent Information and its Use of the Classification System. Patent information activity.
18. Search for patent information Patent research and their role in the development of scientific and technological progress.
19. Licensing agreement as a legal form of transfer of rights to industrial property.
20. Mandatory details of the license agreements.
21. The procedure for payments under license agreements. Establishing Royalty.
22. License concept, definition and its characteristics.
23. The license agreement, general characteristics and features and legal nature of the license agreement.
24. Classification of license agreements. The subject and object of the license agreement.
25. Subjects of the License Agreement, Rights and Obligations of the Parties - Licensor and Licensee.

26. Structure of the license agreement, characteristics of sections of the contract.
27. The procedure for conclusion and registration of license agreements in Ukraine.
28. Licensing of its species.
29. Establishing royalties under a license agreement.
30. Forecasting the development of new technologies. Economic evaluation of innovative solutions.

### **13. RECOMMENDED LITERATURE**

1. Fisher, M., 2007. Fundamentals of Patent Law: Interpretation and scope of protection. Bloomsbury Publishing.
2. Grubb, P. W., Thomsen, P. R., Wright, G., & Hoxie, T. (1999). Patents for chemicals, pharmaceuticals and biotechnology: fundamentals of global law, practice and strategy (p. 1867). Oxford: Oxford University Press.

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