



STATE  
INTELLECTUAL  
PROPERTY  
OFFICE OF  
THE REPUBLIC  
OF CROATIA

# **CURRENT CHALLENGES IN INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICALS**

*WIPO INTERNATIONAL SEMINAR*

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# **I. PRESENT STATUS IN THE REPUBLIC OF CROATIA**

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- INTELLECTUAL PROPERTY AND PHARMACEUTICALS
- ACCESS TO MEDICINE
- BIOETHICS

## II. CASE STUDES

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- SECOND MEDICAL USE
- BIOETHICS

# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTRODUCTION*

- SIPO of the Republic of Croatia was founded in December 1991.
- Patent applications since 1992  
(including nostrifications of patent rights granted by the former Yugoslav Patent Office)
- about one hundred employees presently
  - 25 in Patents ( 15 patent examiners)

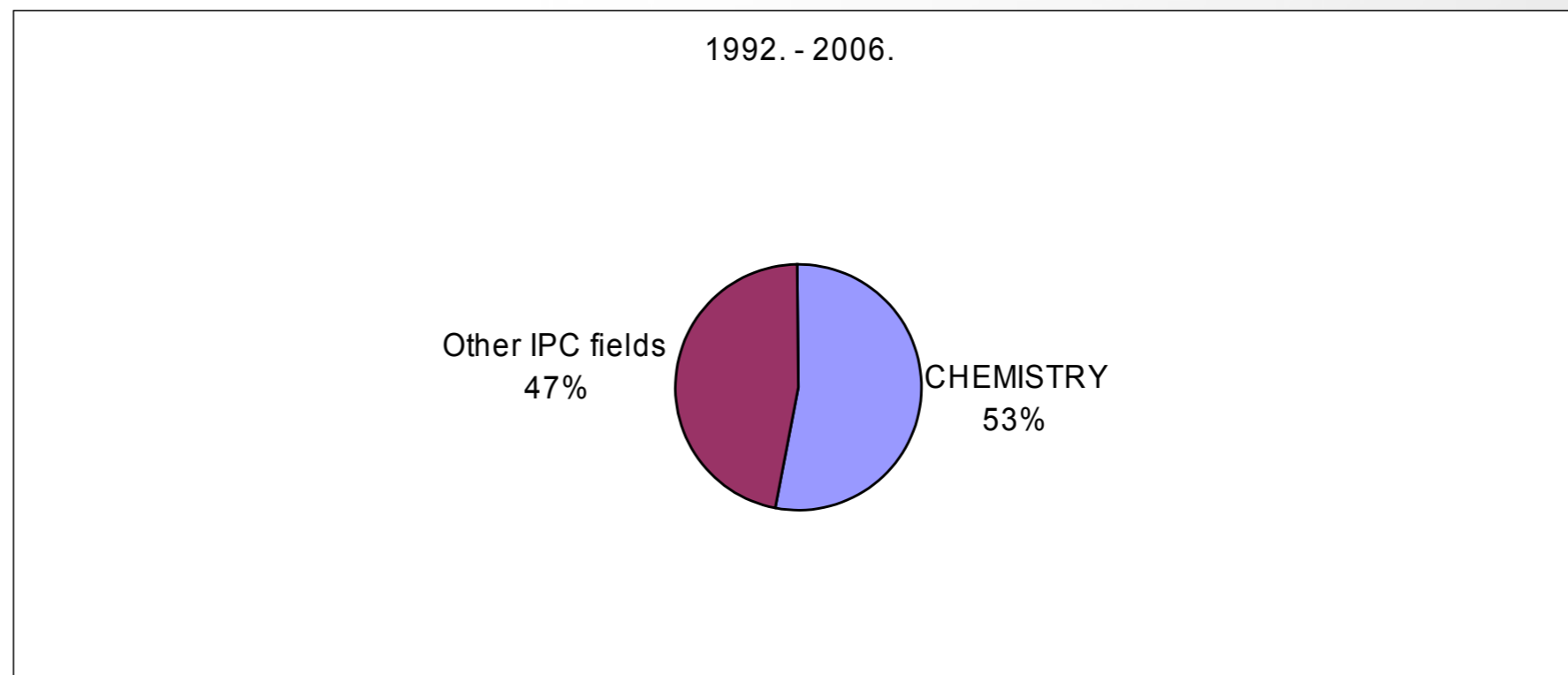
# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

### PATENT APPLICATIONS

Ratio of the chemistry field applications in total amount of patent applications filed in SIPO Croatia in the period from 1992 – 2006



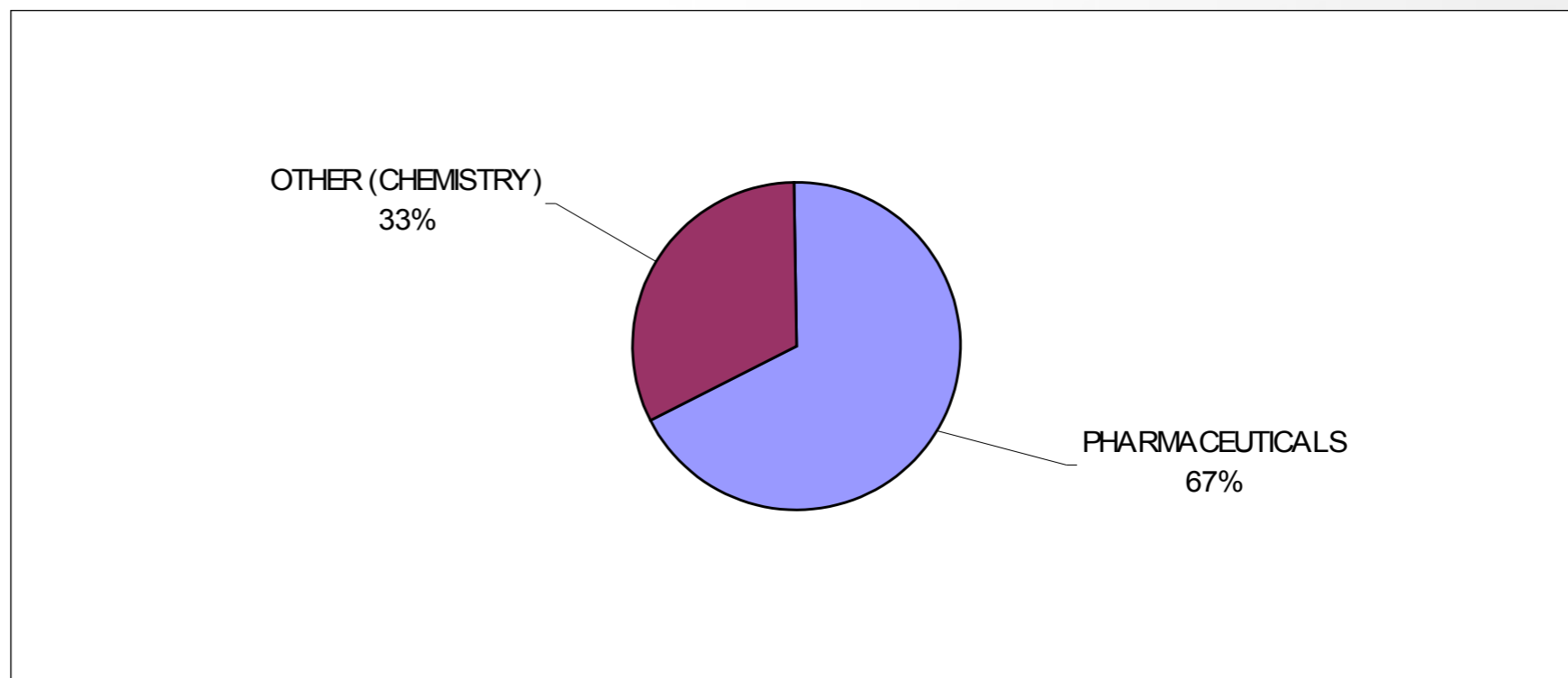
# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

### PHARMACEUTICAL\* PATENT APPLICATIONS

Ratio of the pharmaceutical applications in total amount of chemistry applications filed in SIPO Croatia in the period from 1992 – 2006



\* Pharmaceutical patent applications amount to 36% of the total number of the patent applications filed in SIPO Croatia in the period from 1992 - 2006

# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

## INTELLECTUAL PROPERTY AND PHARMACEUTICALS

### CROATIAN PATENT ACTS

Comparative analysis of various Patent Acts provisions relevant for pharmaceutical inventions

Relevant Croatian Patent Act	Patent for a process(*) (=product)	"Bolar" provision	Second medical use	SPC	Compulsory Licence for patents on pharmaceut. products
- in force	1	2	3	4	5
- 1991 - 1993 (based on the Yugoslav Pat. Act)	+	-	-	-	-
- 1. 01. 2000	+	+	-	-	-
- 1. 01. 2004	+	+	+	+(Application deferred until 2010)	-
-Amendments (planned: 1.01 2008)	+	+	+	+(Application deferred up to the accession of Croatia to the EU)	+

(\*) Earlier, in pharmaceutical patents only for a process, but not for the product directly obtained from that process.



# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

### PROVISIONS RELEVANT FOR PHARMACEUTICALS :

1. *Under the current PATENT ACT ( in force:  
January, 2004 )*

- Patent for a process

*Article 58(2) (Exclusive rights acquired by a patent)*

Any other person not having the patent owner's consent shall be prohibited from:

3. offering for sale, selling, using , exporting or importing and stocking for such purposes, the product which is obtained directly from a process which is the subject-matter of the invention.



# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

- Bolar provision

### *Article 63. (Exceptions to the exclusive rights)*

2. acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for obtaining registration or authorization for putting on the market a product being a human drug or a veterinary product or a medical product,

# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

- Second medical use

### *Article 8 ( Novelty of an invention)*

(4) The provisions laid down in paragraphs (1) to (3) of this Article shall not exclude the possibility for patent protection of substances or compositions forming part of the state of the art, and used in processes referred to in Article 6, paragraph (3) of this Act, provided that their use in the mentioned processes does not form part of the state of the art.

# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

- Supplementary Protection Certificate ( SPC ):  
Articles 71-73, and Article 84

*Article 117 ( Deferred application of particular  
provisions of the Act )*

- (1) The application of the provisions laid down in  
Articles 71 – 73 and Article 84 of this Act shall  
start on March 1, 2010.

# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *INTELLECTUAL PROPERTY AND PHARMACEUTICALS*

### PROVISIONS RELEVANT FOR PHARMACEUTICALS:

#### *2. Under the current ACT ON DRUG AND MEDICINAL PRODUCTS\_*

*(Amendments : December, 2004) – Ministry of Health and Social Welfare*

- Data exclusivity

#### Article 15.

The applicant requesting a marketing authorisation for a drug product referred to in Article 14 under this Act, shall not be liable to annex the results of toxicological and pharmacological testing, and the results of clinical testing if the following can prove :

a) that a drug product is identical to a drug product of the original producer, provided that the original producer of a drug product has been granted a marketing authorisation for a drug product in the Republic of Croatia or in one of the Member States of the European Union for more than six years ago and this drug product has been placed on the market of the Republic of Croatia».

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## *ACCESS TO MEDICINE*

FUTURE AMENDMENTS OF PATENT ACT ( to be in force:  
January, 2008 )

Compulsory licensing of patents relating to the  
manufacture of pharmaceutical products for export to  
countries with public health problems;  
( harmonisation with the Regulation EC 816/2006 of the  
European Parliament and of the Council, May 17, 2006)



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## *BIOETHICS*

- CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE : CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE (in force since December 1, 1999)

and

### TWO ADDITIONAL PROTOCOLS:

- Additional Protocol to the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, on the prohibition of cloning human beings;
- Additional Protocol to the Convention on human rights and biomedicine concerning transplantation of organs and tissues of human origin.

- Ratified by the Croatian Parliament on July 14, 2003

# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

## CONCLUSIONS

The impact of legislation changes after harmonisation with EU legislation in the field of pharmaceuticals to the Croatian generic pharmaceutical industry

Provisions relevant for pharmaceuticals	IMPACT
Second medical use	NEUTRAL / NEGATIVE *
SPC (application deferred)	NEGATIVE (prolongation of originator's patent protection)
Compulsory licence for patents on pharmaceuticals (Future amendments)	NEGATIVE (in case of having patent)
"Data exclusivity"	NEGATIVE (delayed marketing authorisation for a generic drug)

(\*) prolongation of originator's patent protection for the substance



# I. PRESENT STATUS IN THE REPUBLIC OF CROATIA

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## *CONCLUSIONS*

Harmonization of the Croatian legislation with the EU *Acquis Communautaire* in the field of pharmaceuticals, has the following consequences :

- on the Croatian Pharmaceutical industry – mainly the generic one :
  - negative influence caused by newly implemented provisions, in particular : SPC and "Data Exclusivity " provision.
  
- on Bioethics :
  - a new "movement" towards resolving problems of the "new age".

## II. CASE STUDIES

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- *Second medical use*

- a) HR- application : P20020249 A

- application of 2002, namely the application that should be examined according the "old" Patent act (of 2000), which did not recognize the institut of "second medical use"

- HR Claim 1:

- "A method of stimulating an immune response comprising administering a Py –rich immunostimulatory nucleic acid to a non-rodent subject in an ammount effective to induce an immune response in the non-rodent subject wherein the nucleic acid is a T-rich nucleic acid that is greater than 60% T and contains a CpG dinucleotide."

- A typical "method for treatment of human or animal body...." claim
    - Search Report shows that compound (Py- rich immunostimulatory nucleic acid wherein the nucleic acid is a T-rich nucleic acid that is greater than.....) - is not new.
    - Result of granting procedure by the Croatian office :

- HR examiner rejected this claim (claim not granted!)

## II. CASE STUDIES

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- *Second medical use*

- b) EP 1 221 955 B1– (the document of EPO granted rights) :
  - reveals that EPO has granted the identical Claim (as of HR P20020249A), that HR examiner has not granted (cause of the HR Patent Act from 2000)
  - EPO has granted the (HR) identical claim, as a second medical use, in the form of "swiss claim".

EPO granted the concerned claim as :

"Use of a Py –rich immunostimulatory nucleic acid, which is a T-rich nucleic acid that is greater than 60% T and contains a CpG dinucleotide, for the manufacture of a medicament for administration to a non-rodent subject in an ammount effective to induce an immune response in the non-rodent subject."

## II. CASE STUDIES

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- *Second medical use*

### HR - PROBLEMS RESULTING FROM SUCH CASES:

- procedural "problems" in the Croatian office
  - resulted from frequent change of Patent Acts

#### Acts

- problem of incontinuity of decisions for the same subject matter

- a) non-granting or
- b) granting

substantially the identical "method of treatment" claims (and also "normal" second medical use claims)

- *Non-granting or granting by HR office depend only on relevant Patent Act force, when application was filed.*

*in*

## II. CASE STUDIES

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- *Second medical use*

a) In case of non-granting (applications filed prior to 1.01. 2004) :

- problems with communication :  
examiner- applicant
- time-consuming and exhaustive procedure  
to explain to applicants ( they  
always try to get more from their claims !)



## II. CASE STUDIES

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- *Second medical use*

b) In case of granting (applications filed after 1.01.2004) :

- Granting by converting "method of treatment" claims to the "second medical use", using "swiss-type" claims, when the active substance is not new.

- good for applicant, but
- may be a problem for domestic (generic) pharmaceutical industry.

# II. CASE STUDIES

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## *2. Bioethics*

or “Eppur si muove”

The famous Croatian gynaecologist in the area of human reproduction and a biologist are recently under the investigation for transplanting egg cells without permission of their patients.

### Newspaper citation :

“They are charged with arranging to apply the method of in vitro fertilisation with the egg cells of other women for a fee during two years, from 2002 through 2004, in a gynaecology and cytology diagnostic clinic. The fertilisation was applied to five patients who were being treated for infertility.

With the aim of performing the said embryotransfers, they used a prepared laboratory embryos from other women who were in the treatment programme in the said clinic due to their own fertility problems, without their knowledge and consent

They performed the fertilisation although they knew that such a method is regulated by positive regulations in the Republic of Croatia.”





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Thank you for your attention !

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