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Constructive alignment analysis and redesign of the Ph.D. course 'Innovation and intellectual property rights in biotechnology'

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1. Introduction:

In this report, I will analyse the Ph.D. course 'Innovation and intellectual property rights in biotechnology'. From next year, this course will be offered by HEALTH instead of LIFE due to the faculty merge, and thus it is expected to attract students with a stronger focus on drug discovery and human health than previously. I will focus on the technical contents of the course and the alignment between intended learning outcomes, learning activities, and assessment. Potential adjustments will be suggested with the aim of facilitating its transition to become a HEALTH course, and to increase the student's learning outcome.

2. What is constructive alignment?

Constructive alignment (CA) is about how to structure and design teaching in order to facilitate deep learning. Some of its fundamental principles

are that clear and stated goals (Intended learning outcomes) induce efficient learning; that learning depends on what the students actively do to obtain it; and that the format and requirements of the exam direct the students´ efforts and behaviour and thus their final learning outcome. According to the original Biggs' CA model from 1999, the following three main elements must match and support each other, i.e. be aligned, in order for the students to engage in deep learning (Rienecker et al. 2013, pp.97-98; Andersen 2010, pp.134):

a Intended learning outcome (The competences we wish to give the students)
b Teaching and learning activities (The format of the teaching, e.g. lectures/classes/exercises)
c Assessment (How it is being measured that the intended learning outcomes are achieved)

For example, if it is a goal (intended learning outcome) that the students should become able to use bioinformatics and patent data bases to evaluate the 'freedom-to-operate' situation of a potential invention, the course is badly aligned if this competence is not being practiced during the course (but perhaps only theoretically described). So, to obtain alignment, intended learning outcome and teaching/learning activities must correlate and support each other. Likewise, if the final exam does not reflect what has been taught or practiced (e.g. demonstrate the use of databases to solve tasks versus only demonstrating their awareness of these databases), or reflect the expected learning outcome, the course is misaligned.

But why is CA important? Although not everyone agrees that focusing on CA is beneficial (e.g. some raises the argument that a rigid focus on CA simplifies university pedagogy and lead to a narrow-minded and technocratic mentality, (Andersen 2010)the supporters point out that CA:

- Assures that student-activities that aid the intended learning are applied (Rienecker et al. 2013, pp.97; Andersen 2010)
- Assures that the final exam/assessment is designed in a way that guides the students' efforts in the desired way. E.g. if deep understanding and analytical skills are required for passing the exam this is known by the students and thus incite them to obtain these competences (Rienecker et al. 2013, pp.98; Andersen 2010).

- Guides the students, leading to less frustration and disappointment and more ‘fairness’ in the assessment. The students ’know’ which competences are required for the final exam (Grønbæk & Winsløw 2003).
- Provides a useful tool for the teacher when preparing. If goals (intended learning objectives) are clear, it is easier to prepare and adjust the teaching accordingly (Grønbæk & Winsløw 2003).
- Provides a tool for dissecting a course into its essential elements, which is useful when analysing and (re)evaluating/designing courses (Grønbæk & Winsløw 2003).

The principles of CA have now been integrated in Danish education law (Rienecker et al. 2013, pp.134), and e.g. the goals of each course must be described. Formally, teaching goals must be expressed by the ‘skills’, ‘knowledge’ and ‘competences’ acquired by the students (Rienecker et al. 2013, pp.134). Without engaging in a semantic discussion of these terms (but see (Rienecker et al. 2013, pp.134-140) if interested), it is a general trend in modern university pedagogy that goals are described by ‘competences’, where competences are skills and knowledge that can be combined, integrated and applied in a practical and professional situation (Andersen 2010, Grønbæk & Winsløw 2003). Also, the competences can be adapted and thus used in other perhaps more advanced situations later on. Thus, in its essence, phrasing competences is about describing what exactly the students will become capable of doing in a professional setting or at their following level of education. Clearly, the goals (or intended learning objectives) are so fundamental in CA, as they affect teaching activities, assessment, and thereby the final learning outcome. Therefore, it is essential to phrase the goals in a manner that facilitates high quality. There is a vast amount of literature and guidelines how to do that (Rienecker et al. 2013, pp.133-145; Grønbæk & Winsløw 2003; Bowden 2004) but generally the trend is to describe competences using the behavioural verbs from the SOLO taxonomy (Rienecker et al. 2013, pp.101-102, 141; Appendix A), which relates to an increasing level and complexity of learning and competences. If used correctly and precisely, this should lead to meaningful, clear and operational goals, which guide both teachers and students in their work. Also, in line with this, Bowden suggests that a useful approach is to first ask, which competences are requested in working life, and then ascertain that the final exam assesses these competences. Then goals and teaching activities form naturally thereafter (Bowden 2004).

CA is relevant at several levels. CA should be considered within each individual course (as discussed above); but also, within each individual teaching 'event' (lecture/lesson/exercise) it is relevant to think about if intended learning outcomes align with the activities, and if assessment is sufficiently implemented to support learning (Rienecker et al. 2013, pp.147). Finally, CA is relevant at the 'external' level, meaning that each course should be aligned with the study plan of the education, so it is clear how the specific courses contribute to the competence goals of the education.

3. Description of the course in the current 'LIFE' version

General info:
The course has been hosted for 5 years by the Dep. of Plant and Environmental Sciences at the Faculty of LIFE (now part of SCIENCE), University of Copenhagen. It is a 1-week course (4 ECTS) aimed at PhD students as well as scientists from industry (26 participants in 2013). Prof. Peter Ulvskov has established the course and served as course leader. The teachers are university researchers with entrepreneurial experience from both Sweden and Denmark, experts in IPR (intellectual property rights), entrepreneurs, research directors from biotech, Tech Trans experts, and venture capitalists. In 2013, 18 different teachers taught the course. Course home page is: http://www.dias.kvl.dk/iprforphds.html. Below is found a description of key elements of the course:

Technical contents: When analyzing the 2013 scheme (Appendix B), it is seen that the number of exercises (incl. round table discussions) were 10, and the number of lectures (incl. demonstrations) were 22; and that each day comprised both kinds of teaching. The subjects being covered in the lectures and exercises can be divided into categories revealing the main themes of the course:

- IPR (in general): 4 lectures and 6 exercises
- (small molecules): 3 lectures and 1 exercise
- IPR (genetics): 1 lecture and 1 exercise
- Business plans and addressing investors: 3 lectures and 2 exercises
- Market potential/analysis: 3 lectures
- Entrepreneurial case studies: 3 lectures
- Biotech (as a business): 2 lectures

- Various: 3 lectures (Stem cells in biotech, Innovation management, BBIP master program)

The material for the course comprise a text book (Patenting in Biotechnology, a laboratory manual) by Peter Ulvskov, and documents that must be read before course (4 'R' document), browsed before course and then read during course (4 'B' documents), or printed to the exercises (8 'P' documents).

Intended learning outcomes:
From the course description ('målbeskrivelsen')[1] it is seen that the *overall aims* of the course are: "to stimulate integration of patenting and innovation in the research laboratories and enable the course participants to tap into the knowledgebase that patents represent"
...and:
"to endow the participants with concrete skills in finding patents and patent applications, recognizing relevant document types and judging the strength of the patents or applications on the basis of an understanding of the patenting process."

More specifically, it is stated that students who met the objectives of the course will be able to:

1. Make participants familiar with the steps required in developing biotechnological products e.g. new drugs
2. Provide knowledge about defining and identifying a commercially interesting problem
3. Enable the participants in navigating the patent landscape surrounding the product
4. Introduction to business plans and raising venture capital for the new company

Teaching and learning activities: The course comprise a series of lectures and parallel case studies. Patenting and use of patent literature and databases are taught in computer exercises. Case studies of business plans and the founding of new biotech companies will be supplemented with discussions with invited entrepreneurs.

[1] Currently the project description cannot be found at the course home page as the course is being redesigned. The course description has instead been acquired from Prof. Peter Ulvskov (personal communication).

Assessment:

At the last course day there will be a 1.5 hour written exam. Aids are pen and hand-written notes.

Course evaluations:

Evaluations from 2013 were very positive. The students were asked to grade each lecture and exercise from 0-3 (where 3 is best) with respect to relevance, quality, and time allocated. Generally, the allocated time for the exercises was sufficient (only minor adjustments are necessary), and the average grade was 2.6 and 2.5 with respect to relevance and quality, respectively.

4. Redesign and adjustments of the course into its new 'HEALTH' version

Technical contents:

Overall, I believe that the course covers important IPR-related topics of common relevance to students no matter their institutional background, such as obviousness, novelty, freedom-to-operate analysis, institutions involved, how to read, file and pursue patents, and how to search in patent literature using databases. Also, market analysis, business plans and strategies for addressing investors and establishing capital are of general relevance. Thus, these topics constitute the core of the course and should remain.

Because the course from now on will be offered by HEALTH, and more specifically by the 'Drug research Academy (DRA)' Ph.D. school (located at Dep. of Drug Design and Pharmacology) future students most likely anticipate a certain focus or bias towards drug discovery and medical aspects of patenting. Also, it is the course leaders´ wish that the content reflects the background of the students and teachers, and the institution that is hosting the course. However, as the course already covers specific drug discovery related examples (e.g. small molecules and genetics) only a few adjustments are found necessary as proposed here:

1. Introduce a lecture and exercise that covers the subjects of 'Biopharmaceuticals', which is a growing field and highly relevant for the stu-

dents at HEATLH. - It has now been arranged that a person from Novo Nordisk will give a talk where he describes the challenges of patenting peptides/proteins (and derivatives thereof) as drugs.
2. The subject of patent mitigation could/should be covered by a person from industry working with small molecules (e.g. Lundbeck), as in previous years of the course.
3. The 'meet an entrepreneur' lesson should be held by a person with a closer relationship to HEATLH (e.g. an internal) so that students better can relate to the entrepreneur and the circumstances of which he managed to start-up a biotech company.

Also, a suggestion is to group the course into 'themes' so the main subjects of the course become very clear. This could be done with headlines on the scheme, and by covering one theme per day

Intended learning outcomes:
DRA (the institution that will now host the course) only has some very general visions and goals (http://dra.ku.dk/about/vision) and no specific intended learning objectives. But still, from these and general knowledge of DRA it is obvious that the current course offers competences highly relevant for the students enrolled at DRA (and likely also for other Ph.D. schools within the areas of medical sciences and biotechnology), so the 'external CA' seems to be fine.

The overall aims of the course as phrased now ("*. . . stimulate integration of patenting and innovation in the research . . . enable the course participants to tap into the knowledgebase that patents represent. . . concrete skills in finding patents and patent applications, recognizing relevant document types and judging the strength of the patents or applications. . .* ") are in my view accurate and covers the key aspects of the course. Subsequently, they must be substantiated by concrete and precise intended learning objectives that describe the specific competences possible to obtain. Thus, in appendix 3, I propose a new set of intended learning objectives based on behavioural verbs from the SOLO taxonomy in an attempt to make the goals more clear and operational (i.e. so that both students and teachers know what to do to achieve the goals). The goals as such are covered by the current as well as adjusted course format and content, but perhaps these phrasings provide more concrete and practical goals that also reflect an increasing level of learning complexity. Also, I have asked myself which competences are needed if/when you want to become a biotech-entrepreneur cf.

(Bowden 2004), and incorporated these skill sets into the goals starting with the most fundamental ones.

Teaching and learning activities:
The course already mixes different teaching styles (lessons, computer exercises, round table discussions), and I believe these support the intended learning objectives. For example, the use of computer-exercises for practicing the use and enhancing the knowledge of patent databases is an essential element of the course, as it provides the students with concrete skills that are practical applicable and relevant for their future work.

Assessment:
The current written exam is a practical and efficient assessment method; and, based on last year's exam questions, allows examination in a wide range of subjects. The exam questions first assess competences from the medium complexity level (identify, combine, describe; cf. SOLO taxonomy), but in order to get full points more complex competences (e.g. analyze, compare, reflect) must be applied. However, in order to better assess if the desired competences of using patent databases, analyzing freedom-to-operate situations, and perform market analyses have been acquired (Appendix 3, point c-e) the exam could include the use of patent databases and/or internet. Thereby the exam would mimic the 'real' professional situation, and assess on skill sets relevant and important in future work situations cf. (Bowden 2004). In line with this, the exam could also be replaced with a case-oriented assignment or presentation (potentially in groups) where such aspects of the course are covered. However, it must be considered if such a format would compromise the 1-week duration of the course, or could require extensive homework by the students.

5. Conclusion and Discussion

The course 'Innovation and intellectual property rights in biotechnology' has been analyzed with respect to its contents and CA; especially considering that the course will be provided by HEALTH (and DRA) instead of LIFE in the future, and thereby that a certain focus on drug discovery and medical science aspects of patenting and biotech is expected and desired.

In its contents, the course was found to already cover general relevant and key aspects of patenting and biotechnology, and also to contain the ap-

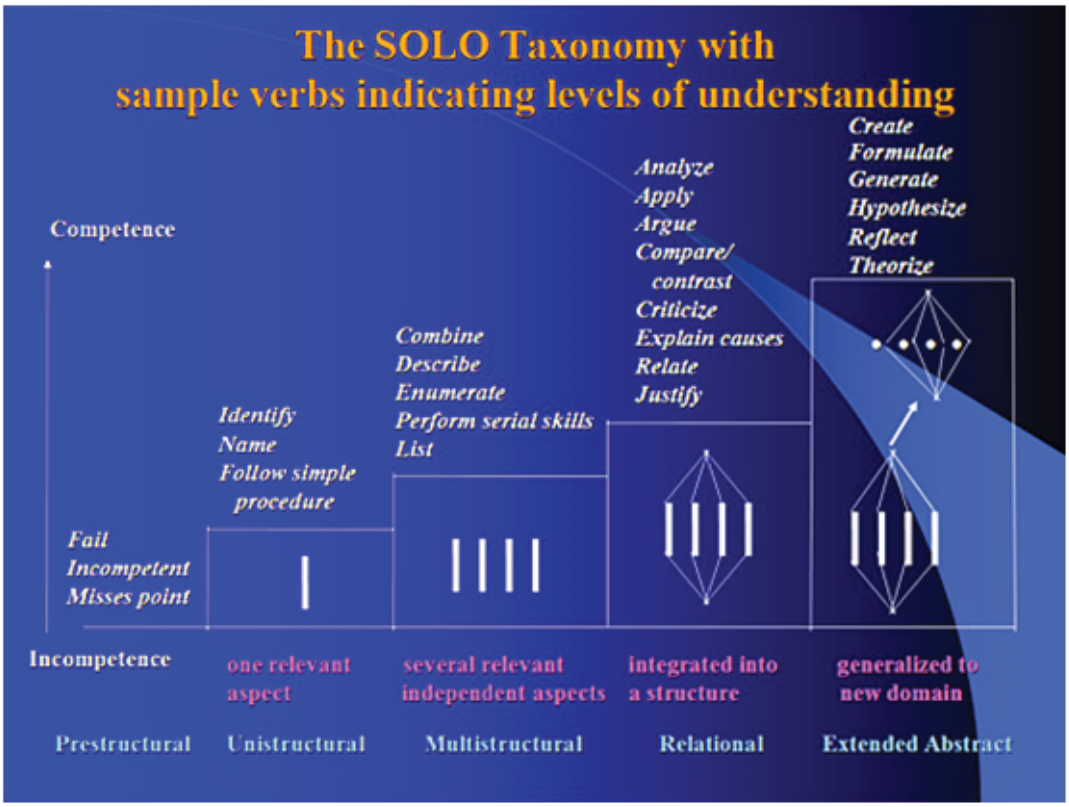
propriate drug discovery examples (e.g. small molecules). Therefore, only minor modifications, such as including the topic of biopharmaceuticals and adjusting the 'meet an entrepreneur' session, was found necessary.

It was found that the course in its 'LIFE format' was generally well-aligned; but that a few adjustments could strengthen the CA even further:

First, a new set of intended learning objectives were proposed (Appendix C) in an attempt to clarify the goals, make the acquired competences more practical applicable, and emphasize their relevance to 'real' working situations. However, this expanded goal description might appear too technocratic or dull in some people´s ear, why it might be necessary to simplify or modify the text in order to ascertain that the course still seem exciting and relevant for the students.

Secondly, it is considered if the assessment format could be changed into a more practical relevant exam or a case-oriented assignment/presentation. This would mimic the real-life situation more closely, and could assess both concrete competences of importance (e.g. use of patent databases) and their ability to analyse (e.g. patent and business situations). If such an assessment will be implemented it is important to emphasize this early at the course, so that the examination form can affect the behaviour of the students in the desired way.

A The SOLO taxonomy



B Scheme for 'Innovation and intellectual property rights in biotechnology' in 2013

Monday January 28	
9.00 - 9.30	Presentation of the course Peter Ulvskov
9.30-10.45	The Shrinking State of Biotech Ecosystem and New Organizational Forms Serden Ozcan
11.00 - 12.00	Introduction to intellectual property rights Peter Horn Møller
13.00 - 13.45	Patentability 1 Peter Horn Møller
14.00 - 15.00	Exercise: Search strategies, profiles and boolean algebra Peter Ulvskov, Bodil Jørgensen
15.15 - 16.00	"Refining the Biotech Model" The Future & How to Get There Øystein Rist
16.00 - 16.30	Introduction of market analysis, NABC, and assignment of homework. Hand-out Morten Heide
Tuesday January 29	
9.00 - 10.00	Exercise: Reading a patent 1, and homework assignment for Reading a patent 2 Peter Ulvskov
10.00 - 10.15	Group planning of Patent reading class 2
10.15 - 11.00	Small-molecules in drug discovery - real life examples John Nielsen
11.15 - 11.45	Protecting low molecular weight compounds Peter Horn Møller
12.45 - 13.30	Demonstration: Searching patents based on chemical structure using SciFinder Christian Skotte
13.30 - 14.30	Exercise: Searching patents based on chemical structure using SciFinder. John Nielsen and Christian Skotte
14.45 - 15.30	Business plan groupwork at the library Morten Heide
15.30 - 16.30	Business plan, a roundtable discussion based on groupwork Morten Heide
Wednesday January 30	
9.00- 9.45	The patent system and its institutions: EPO, USPTO, PCT and the main differences between Europe and USA Peter Horn Møller
9.45 - 10.45	Patentability 2 with particular emphasis on biotech innovations (patenting of genes....) Peter Horn Møller
11.00-11.45	Mirrx and learnings from litigation Thorleif Møller
12.30 - 13.15	The life of a patent: submission strategies Peter Horn Møller
13.15 - 14.15	Exercise: Patent searching in Derwent 2, produce a hierarchical search profile Bodil Jørgensen and Peter Ulvskov
14.30 - 15.00	Meet an entrepreneur Morten Buch-Pedersen
15.00 - 15.30	Exercise: Patents search based on genetic sequence Peter Ulvskov and Bodil Jørgensen
15.30 - 16.15	Stem cells and the European Biotech Directive. Timo Minssen
16.15 - 16.45	Group work on patent reading class

Thursday January 31

9.00 - 10.15	Exercise: Using Patent Register, patent families and All Documents. Produce a patent family tree. Peter Ulvskov and Bodil Jørgensen
10.15 - 11.15	Market analysis - a practical approach. Maria Andersson
11.25 - 12.00	Market evaluation using the NABC approach and mitigating the risks. Maria Andersson
13.00 - 14.00	Collodial Resources Karin Bryskhe
14.15 - 15.00	Exam discussion - questions and answers Peter Ulvskov and Peter Horn Møller
15.10 - 16.30	Exercise: Patent reading class 2 Peter Ulvskov □

Friday February 1

9.00 - 10.00	From Innovative to innovation: Know your customers and prepare them. Perspectives from the pharmaceutical industry Lars Brøchner
10.00 - 10.35	The High Technology Foundation Thomas Bjerre
10.45 - 11.15	PUFA a case study in radical innovation management Anders Grauslund
11.15 - 12.00	The entrepreneurial support ecosystem Peter Conrad Ottesen
13.00 - 13.45	Zealand Pharma and the BBIP master program David Solomon
13.45 - 14.15	Discussion and course evaluation Peter Ulvskov
14.30 - 16.00	Written exam

C Proposed intended learning objectives for 'Innovation and intellectual property rights in biotechnology':

A student who has met the objectives of the course will be able to:

A) Describe and explain the composition of patents within drug discovery and biotechnology, the rationale behind the different sections, and recognise the different types of patents. This includes: structural claims of small molecules and sequences (DNA/Protein); how to patent cells (e.g. stem cells), methods and technologies (e.g. assays); and 'use patents'.
B) Explain the different stages of the patenting process, and requirements for obtaining a patent.
C) Use the various databases to find the relevant patents and patent applications; and to recognize the different document types covering a given invention.
D) To be able to assess the strength and freedom-to-operate situation of a patent based on the obtained understanding and knowledge of patents, the patenting process, and databases.
E) Analyze and discuss the commercial potential of biotechnological ideas and inventions based on the technology platform, IP situation, and market analyses.
F) Describe and compare the different means to fund or finance inventions in order to commercialize these.

All contributions to this volume can be found at:

http://www.ind.ku.dk/publikationer/up_projekter/2014-7/

The bibliography can be found at:

http://www.ind.ku.dk/publikationer/up_projekter/

kapitler/2014_vol7_nr1-2_bibliography.pdf/