# *UC*'s vs. *Broad*'s CRISPRPatents & the Supreme Court's Framework PART III
## or
# By AI Recognized: Any mratBIOETCI is Truly SPL-Robust. 1.a)/b)

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## SECTION I. AI Shows: Any 'mratBIOETCI' is Truly SPL-ratRobust, i.e. Satisfies in ratKR 35 USC/SPL.

This mail's PARTs I & II stated: ●These 2 CRISPRETCIs are nPE (but probably transformable into PE). ●Any CRISPRETCI is by AI automatically testable for satisfying SPL. ●Professionally different communities are involved in a single CRISPRETCI, being one of the reasons for needing its true robustness[c]. ●…..

Its PART III shows anybody, also to BIOnovices: mratBIOETCI-patents are a priori already truly robust. To this end it first familiarizes her/him, in Section II, with clarified key BIOnotions. While she/he often feels to know all that already, this is always far from true, also for BIO_or_SPLtech professionals. I.e., BIOtech deficiencies are not yet recognized in a notional precision as indispensable for truly robust patents on BIOETCIs.

Sections III&IV discuss these intricacies as required in 'hi end' IT systems by 3 BIOETCI-specifications[6.c] — i.e. in the broadly approved '**IT specification technique**' [2], yet in rigorously simplified KR & being powerful enough for scientifically proving by AI[b] of a today's mratBIOETCI that it is truly robust. Hence, Section V proves mathematically a groundbreaking theorem — hitherto **unthinkable** — saying:

> An mratBIOETCI is a priori truly ●PE-robust and ●PA-/SPL-robust for all mratRS$^{SD}$ >1.

This multipart mail is worldwide unique: Today there is no other reliable expertise in one group covering all 4 scientific areas[2] involved in BIOpatenting — AI ∧ System Design ∧ BIOtech ∧ SPLtech[182] — due to the authors' academic CVs, business successes, and being a kind of "knowledge dinos".[e]

## SECTION II. Today's BIOTerminology is ●Murky & BIOETCIs' KR is ●Negligent & ●Framework-Unaware.

These 3 today deficiencies as to drafting BIOETCIs are broadly ignored, though rendering their patent(application)s often so vaguely that they fail meeting 35 USC/SPL requirements — shown here & in Sections III by the 2 CRISPRETCIs' & a *Myriad*-DNAETCI's wordings, in Section IV very briefly as to BIOfundamentals.

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1 .a **Upfront:** The USPTO just published its §§ 101&112 Guidelines[8.f]. It fulfills our expectations that it would adjust its interpretation of 35 USC/SPL exactly to that of the Supreme Court, expressed by its 'SPL-framework' — since about 2008[5] scientifically elaborated on by us to become "**FSTP Technology**".
The Supreme Court defined its **'framework'** by its *KSR/Bilski/Mayo/Myriad/Biosig/Alice* decisions, implicitly refining classic SPL-meanings & inducing 4 categories in thinking of "**KR-qualities**"[2] 'mphys ⊃ mrat ⊃ rat ≈ mat' in SPL⊂IPR[489ft2.b)] — often skippable, e.g. at first reading or evidently.

.b [**ET**]**CI** denotes '[Emerging Technology] Claimed Invention' — in 'Facts Screening/Transforming/Presenting, **FSTP**'-terminology of the AI based subject matter and ETCIs modelling language 'Innovation Definition Language, **IDL**'; **AI** 'deterministic AI'; **SPL** 'Substantive Patent Law'; **NPS** 'national patent system'; ……..**cont'd to**[7.b].
Assumed is also basic familiarity with the scientific clarification of the untenability of the CAFC's and USPTO's (until recently) grossly coarsening the Supreme Court's '**patent-eligibility**, **PE/nPE**' specification in its *Alice* decision — explained in[e.g. 458,…,500] and drafted to be very short yet easily comprehensible. Finally: This FSTP-mail does not repeat all earlier FSTP-clarifications of the Supreme Court's SPL-framework refinement, which it repeatedly ex- or implicitly invited[e.g. 458ftn1.c)]. It also does not go into analogously to SPL modelling SCRL and STML.[182]

.c The meaning of '**true** mrat/rat(PE resp. SPL|PA)**robustness**' of a patent's ETCI is defined as its (PE- resp. SPL|PA -ratsatisfying by ratCOM(ETCI) – not only part of it.

.d ratKR terminology is not always of concern in BIOR&D, as it is partially dispensable for scientification/mathematization of true SPL-robustness[c]. Yet, freestyle stating it by the **poposc** or an examiner is for investors in BIOETCIs no more trustworthy. Also, Wikipedia's genetic glossary seems at a first glance as of little help, because it has not yet rat/matspecs. But, for a BIOETCI's scientification/mathematization the latter is not needed as its KRmrat suffices[182].
In total, today's BIOterminology has untenable deficiencies. Not clarifying them would devaluate patents using them, especially for investors[3.b].

.e In the US and internationally holds: No public or private market, or health organization, or court, or PTO has this factual and SPL expertise about this for all men extremely important but multiply sophisticated and intricate BIOETCIs' patenting area as required by inventors and investors.

**II.1** [BIO]**Terminology is Murky:** Today the most evident problem in patenting [BIO]ETCIs is [BIO]research's reluctance to use a Genetics' term/name/meaning[489ftn2.a)] for only 1 [BIO]item, i.e. often to unintentionally induce different DNA-terms had the same meanings or different meanings were the same, while this is untrue. Put harshly: **Today's Molecular Biological terms are often ambiguous, false, or misleading**. On this basis, no examiner, no patent lawyer, and no judge has a chance to deliver decent results of her/his [BIO]work.

Biopolymers like nucleic acids, proteins, lipids, or carbohydrates, but also the plethora of non-polymeric molecules of cellular metabolism or intra- and intercellular signaling were never assigned a consistent and logical terminology. Consequently, the functions associated with or derived from interactions of such molecules are described by a merely free-floating realm of historical, inventor-based, associative, or even non-sense terms, annotations, and abbreviations.

Though communication between scientists from similar fields, e.g. biochemistry, molecular biology, genetics, bioinformatics, is easily accomplished by using such terms, understanding becomes difficult or goes astray, if the common context is left. Evidently, and as exemplified by the use of molecular biological terms in both the UC (Doudna) and the Broad/MIT/Harvard (Zhang) patents, this is the case, if scientific descriptions need to be adapted for patenting, as here deeply heterogeneous cultures must cooperate.

If terms are either not unequivocally defined or different terms are applied for one-and-the-same biological function, patents will run into endless litigations and expensive lawsuits. Even more important, any exact science based computational approach to the analysis of patent(application)s – as elaborate and AI it may be – will ultimately fail under these conditions. It's a colloquial but consequent saying that "trash in means trash out".

Here, we applied the above criticism to the first claims of the UC and Broad/MIT/Harvard patents on the CRISPR-Cas9 gene editing technology. Note that we nowhere discuss in this mail the fact that both patents commit for their ETCIs under-specifications of different kinds – which trivially are legal errors.

### US 8,697,359 B1 (Broad/MIT/Harvard) [2.b)]

1) Claim 1 (with extending claims 2-7) claims the *"method of altering expression of .... gene product"* in a "eukaryotic cell" that has a *"target sequence"* and where the targeted sequence is *"encoding the gene product"*. This requires or is accomplished by introducing into the eukaryotic cell two DNA-based expression constructs, referred to as *"comprising one or more vectors"*. One DNA-based expression construct *"vector"* drives (regulates) the expression of an RNA gene, i.e. the *"guide RNA"*. The other DNA-based expression construct *"vector"* drives (regulates) the expression of a protein gene, i.e. the *"CRISPR associated (Cas)"* protein.

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[2] **.a** **[***UC***-ETCI[1/X]]:** *"A method of modifying target DNA molecule[(1)], the method comprising: contacting[(α)] a target DNA molecule having a target sequence with a complex[(α)] comprising: (a) a Cas9 protein; and (b) a DNA-targeting RNA comprising: (i) a targeter-RNA that hybridizes with the target sequence; and (ii) an activator-RNA that hybridizes with the targeter-RNA to form a double-stranded RNA (dsRNA) duplex of a protein-binding segment, wherein the activator-RNA hybridizes with the targeter-RNA to form a total of 10 to 15 base-pairs, wherein said contacting takes place outside of a bacterial cell and outside of an archaeal cell, thereby resulting in modification of the target DNA molecule* **[**whereby any disease of the set {D1, D2, D3, …} disappears, if the resp. indicator {I(D1), I(D2), I(ID3), …} this signals**].**[c)]*"*

**.b** **[***Broad***-ETCI[1/Y]]:** *"A method of altering expression of at least one gene product comprising introducing into[(β)] a eukaryotic cell containing and expressing a DNA molecule having a target sequence and encoding the gene product[(β)] an engineered, non-naturally occurring […] CRISPR-Cas system comprising one or more vectors comprising: a) a first regulatory element operable in a eukaryotic cell operably linked to at least one nucleotide sequence encoding a CRISPR-Cas system guide RNA that hybridizes with the target sequence, and b) a second regulatory element operable in a eukaryotic cell operably linked to a nucleotide sequence encoding a Type-II Cas9 protein, wherein components (a) and (b) are located on same or different vectors of the system, whereby the guide RNA targets the target sequence and the Cas9 protein cleaves the DNA molecule, whereby expression of the at least one gene product is altered; and, wherein the Cas9 protein and the guide RNA do not naturally occur together* **[**whereby any disease of the set {D1, D2, D3, …} disappears, if the resp. indicator {I(D1), I(D2), I(D3), …} this signals**].**[c)]*"*

**.c** The in **.a** and **.b** shown round bracketed arabic/greek indices in these original [CRISPR]ETCI wordings identify below comments on such deficiencies. The very recently granted [CRISPR]patents to UC and Broad — by the same inventors as their above patents — don't fix these deficiencies. **.a** and **.b** are of [mphys]KR-quality[1.a)], in[5.b)] their [mrat]KRs are presented. Thereby holds principally for any ETCI: [mphys]KR<[mrat]KR≤[rat]KR=[mat]KR. In *Biosig* the Supreme Court states that in unlimited natural language absolute exactness for §112 is unachievable — not so in IDL[e.g.394] and [BIO]IDL.

Thus, the term *"expression"* and homologs alias synonyms thereof is used here for different kinds of gene expression in one and the same sentence: a) expression of one or several gene(s) (the target gene(s) to be modified) of the approximately 30.000 genes of a typical eukaryotic cell, and b) expression from two engineered expression constructs (one coding for the guide RNA, the other for the Cas protein), being introduced into the cell.

2) *"regulatory element operable in a eukaryotic cell"* is a generic term for the regulatory elements required for gene expression, like enhancers, promoters, termination- and poly(A) addition signals. Regulatory elements are generally different in prokaryotes (bacteria) and eukaryotes. Differences are great between plants, insects or animals, i.e. one and the same regulatory element cannot be used for plant gene expression and animal gene expression; regulatory elements often differ between otherwise closely related species .

Here, reasons for putting the regulatory elements into subheadings a) and b) are the following:

Expression of the RNA-coding gene, i.e. the guide RNA referred to under a) requires regulatory elements for gene expression of RNA-coding genes. The expression of the protein-coding gene (the Cas protein referred to under b) requires regulatory elements for gene expression of protein-coding genes.

3) *"the Cas9 protein and the guide RNA do not naturally occur together"*

It says that guide RNA and Cas protein are not molecularly linked and will only interact by sequential physicochemical processes leading to the formation of a stable and functionally active complex between Cas protein and a structural motif in the guide RNA. This is limited in claim 4 to the type of RNA construct actually used in CRISPR-Cas applications and experiments. Here (claim 4), the guide RNA is "fused to a transactivating (tracr) sequence". "Fusion" is not a molecular biological term. Therefore, "fusion" may refer to either guide RNA and tracrRNA as one and the same molecule (as they are used in today's experiments) or fused through hybridization by complementary RNA nucleotides forming a stem-loop (hairpin-like) structure.

**US 10,000,772 B2 (UC)[2.a)]**

1) Like in the Broad/MIT (US 8,697,359 B1) Zhang patent, a *"method"* is claimed first, but instead of claiming *"altering expression of at least one gene product"* (as in Broad/MIT) here, *"modifying a target DNA molecule"* is claimed. Insofar, this is a wider claim than just altering gene expression.

2) The natural CRISPR-Cas9 system in prokaryotes consists of two RNA components. crRNA (CRISPR repeat RNA) which is equivalent to "targeter RNA" and tracrRNA (transactivator RNA) which is equivalent to "activator-RNA". Like crRNA and tracrRNA, also the claimed targeter-RNA and activator-RNA form an RNA::RNA complex (double quotes "::" indicate a physicochemically stable and defined complex) held together by Watson-Crick hydrogen bonds forming a stem-loop structure (a double stranded stem of 10-15 base pairs connected by a short single-stranded loop; this is often called "hairpin"). The hairpin formed between crRNA and tracrRNA does not lead to a contiguous RNA molecule, because it contains a "nick" (a single-stranded break) separating the RNA backbones of crRNA and tracrRNA.

This is different to the gRNA (guide RNA) in the Zhang patent, though a very similar hairpin is formed. However, the gRNA is one contiguous RNA molecule (with no "nick" in its RNA backbone).

3) *"Outside of a bacterial cell and outside of an archaeal cell"* excludes use of the method in the two biological kingdoms where the method naturally belongs to. It could mean to operate only outside of cells (only in vitro but not in vivo), but could also be seen as functioning in vitro as well as in vivo but with prokaryotes being excluded.

4) Claim 2 defines *"modification of target DNA molecule"* as *"cleavage of the target DNA molecule"*. Again, this is a wider claim than in the Zhang patent, because cleavage may be followed by a number of different cell biological events and not just altering gene expression.

5) *"Chromosomal DNA"* could indicate intracellular DNA, but ambiguous interpretations are possible.

From both patents becomes evident that the most questionable terms, as exemplified above, are:

- gene expression
- vector
- hybridization or hybridizing
- contacting or complex

We will define their meanings and explain the use of better terms in the following — as a starting point for AI's needed increase in exactness[3.b)]. As a reference may serve any of several well established student textbooks of Biochemistry/Molecular Biology, e.g.: "Molecular Biology of the Cell", by B. Alberts, A. Johnson, J. Lewis, D. Morgan, M. Raff, K. Roberts, P. Walter; 6th edition Garland Science.

A) In classical biology "gene expression" covers all molecular processes involved to generate the phenotype as determined by the genotype. It may refer to expression of all genes (the genome) of a species leading to the phenotype of that species, or to the expression of an individual's genome leading to the phenotype of the individual.

In molecular biology and biotechnology derived thereof, "**gene expression**" most often refers to the generation of gene products as determined by a single or by several gene(s). Two types of gene expressions need to be differentiated. Genes of which the gene product is a given RNA molecule (RNA-encoding genes) differ from genes of which the gene product is a given protein molecule (protein-encoding genes).

For RNA-encoding genes, the process of gene expression, i.e. generation of the gene product "RNA", requires qualitatively, quantitatively and time-wise controlled transcription. Though gene expression of RNA-encoding genes is formally a one-step process, for a precise description post-transcriptional processing and post-transcriptional modification have to be taken into account.

For protein encoding genes, i.e. generation of the gene product "protein" gene expression formally is a two-step process. Qualitatively, quantitatively and time-wise controlled transcription (including post-transcriptional processing and post-transcriptional modification) is followed by the process of translation (the genetic information encoded in "nucleic acid language" becomes translated into "protein language"). Again, for a precise description post-translational processing and post-translational modification have to be taken into account.

All the above applies to gene expression from the genome of eukaryotic cells. Focused on the CRISPR-Cas method, these are the target genes intended to be modified.

We therefore strictly recommend using the term "gene expression" only for the expression of genes belonging to the genome of a cell in its natural biological environment, i.e. the cell nucleus of a living cell.

In both CRISPR-Cas patent applications two other kinds of "gene expression" are described. One is the generation of the RNA gene products gRNA (Broad/MIT/Harvard), or crRNA, and tracrRNA (UC), the other is the generation of the protein gene product Cas. These "gene expressions" are not encoded by genes belonging to the genome of a cell in its natural environment, but by artificial DNA constructs to drive the intracellular biosynthesis of gene products, which are either RNA (gRNA, crRNA, tracrRNA) or protein (Cas).

We therefore strictly recommend to refer to these "genes" as DNA constructs. The function of such DNA constructs is either biosynthesis of an RNA gene product (DNA constructs for the biosynthesis of gRNA, crRNA, or tracrRNA) or biosynthesis of a protein gene product (DNA constructs for the biosynthesis of Cas).

B) In classical biology "vector" covers either living system (mostly insects, worms, parasites, bacteria) or high molecular, non-living systems (like viruses) which transmit infectious agents (parasites, bacteria, viruses). Here, the vector is just the carrier of the infectious agent, vector and infectious agent are separate entities

In molecular biology the term "**vector**" is used ambiguously. In most cases it refers to an artificial DNA construct for the intracellular biosynthesis of either an RNA or a protein gene product, as described in A). These vectors are termed non-viral vectors. Non-viral vectors usually require additional agents to enable penetration of the highly polar nucleic acid through the rather apolar cellular membrane. The non-viral introduction of a DNA expression construct through the cell membrane into a cell and further into the cell nucleus is termed "transfection".

Conversely, viral vectors (a virus basically is a complex between nucleic acids and proteins) are artificial DNA or RNA constructs complexed with a subset of proteins from the original (wild-type) virus for the intracellular biosynthesis of either an RNA or a protein gene product. This complex (DNA::protein or RNA::protein) enables more efficacious cellular uptake compared to non-viral vectors, but has other disadvantages not discussed here. The viral protein-mediated introduction of a DNA or RNA construct into a cell is often termed "transduction" with reference to the original uptake mechanism of the wild-type virus.

In both patent applications the term vector covers transfection of non-viral vectors as well as transduction of viral vectors. We therefore strictly recommend to explicitly refer to non-viral and viral vectors instead of just using the term "vector".

C) In classical biology the terms "hybrid", "hybridization", or "hybridizing" refer to the generation of non-naturally occurring combinations of phenotypes in plant and animal breeding.

In molecular biology the terms "**hybrid**", "**hybridization**", or "**hybridizing**" almost generally refer to the complex or the formation of a complex between two complementary single strands of nucleic acids, either DNA or RNA. Complementarity is defined by Watson-Crick type base pairing through three hydrogen bonds between Cytosine- and Guanine-nucleotides or two between Thymine and Adenine-nucleotides, respectively.

In the patents at least three types of hybridizations are covered under the terms hybridizing, hybrid, or duplex, leading to ambiguities about the identity of the hybridizing RNA or DNA molecules, as well as the energy requirements and driving forces of the respective hybridization type. In more detail the three types of hybridizations could be described as follows.

The hybridization between crRNA and tracrRNA to form the not covalently closed (nicked) hairpin (UC patent) is purely concentration dependent; thus the higher the concentration of both components, the more efficient hairpin formation (an RNA::RNA duplex) will occur.

The hybridization of the equivalent (orthological) covalently closed (belonging to one-and-the-same RNA molecule) hairpin (Broad/MIT/Harvard patent) is nucleotide sequence dependent; thus the better the inverted repeat sequence motif fits hairpin formation, the more efficient the hairpin in gDNA will form.

Finally, the key event in the CRISPR-Cas method, i.e. the hybrid formed for targeting of the gene to be modified, is an unusual type of hybrid that forms naturally in the genome in rare but specific situations, only. It is termed R-loop hybridization. An R-loop forms when an RNA which is complementary to one strand of the DNA double helix "invades" the DNA double helix (a DNA::DNA duplex), hybridizes to the complementary DNA strand to form an RNA::DNA duplex, and thereby

displaces the non-complementary DNA strand. The non-complementary strand then forms a single stranded loop which is wrapped around but no longer hybridized to its complementary DNA strand.

In the CRISPR-Cas method, R-loop hybridization on the one hand depends on the concentration of the crRNA::tracrRNA duplex (UC patent) or the gRNA (Broad patent) with its hairpin-forming nucleotide sequence motif. On the other one, R-loop hybridization depends on DNA-unwinding function of the activated complex between Cas protein and RNA hairpin (the Cas::gRNA or Cas::tracrRNA complex).

We therefore strictly recommend to specify the components of the duplex formed, i.e. RNA::RNA, DNA::RNA, or DNA::DNA. Even more important, the type of hybridization has to be named. For the CRISPR-Cas method they are RNA duplex hybridization, hairpin or better stem-loop hybridization, and R-loop hybridization.

D) **Contacting** is not a proper term to refer to either hybridization or formation of a molecular complex. There is no action without interaction; thus diffusion-driven molecular motions that lead to "contacting" are necessary but not sufficient for hybridization or complex formation. Hybridization as well as complex formation require proper orientation of the complex-forming molecules to enable non-covalent chemical bonds. These are hydrogen bonds for nucleic acid hybridization and van der Waals forces, hydrophobic interactions (better "entropic effects), or hydrogen bonds in proteins.

All these non-covalent bonds are required in the formation of the Cas::RNA (hairpin RNA) complex. Moreover, complex formation is a sequential process enabling the fully functional complex to drive R-loop formation. The first step is binding of Cas to the hairpin of the crRNA::tracrRNA duplex or in gRNA. This leads to a conformational change in the Cas protein, enabling binding to the "protospacer adjacent motif" (PAM). Successful binding of PAM by Cas leads to another conformational change in Cas, enabling its DNA unwinding activity which allows for invasion of the RNA (crRNA::tracrRNA in the UC patent; gRNA in the Broad/MIT/Harvard patent) to hybridize to the complementary DNA strand, displacing the non-complementary strand, and formation of an R-loop.

We therefore strictly recommend to avoid the term "contacting" and instead name the complex formed and its components. Complexes are usually dimeric, trimeric, or oligomeric. Components are named and separated by delimiting double quotes, like in Cas::RNA::DNA for the complex described above.

Sections III & IV discuss similar vaguenesses caused by patenting[503], helping especially novices in BIOtech areas, by widening their thinking to the Supreme Court's framework — as it provides far reaching relief from today's SPL-obscurities by enabling drafting legally truly robust BIOpatent(application)s .

To put this intermediary result more explicitly: This Section II overcomes much of the above touched on vagueness[3.a)] by its BIOnotional clarification. Yet, additional patenting clarification is needed as basically shown in Section III, elaborated on in Section IV — for enabling drafting[b)] truly robust BIOpatent(application)s of all kinds — before showing in Section V that, for BIOETCIs, the Supreme Court by its SPL-framework has totally removed any such SPL-obscurity and hence BIOETCIs' entire 'under-SPL-testing' problem.

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[3].a In the wake of the steep increase of knowledge in the BIOtech-areas, patent(application)s' specifications of BIOETCIs became ridiculously voluminous — indicating multiple failures to meet, by BIOETCIs, the § 112 requirements. I.e., their inventors & investors would be better off if they dramatically reduced this paperwork and instead strived for their BIOETCIs' robustness, in line with the Supreme Court's reinterpretation of 35 USC/SPL. Since its framework decisions, it is obvious that it is in favor of ETCIs and hence provided by its *Mayo*/*Myriad*/*Alice* decisions PE guidelines of Solomonic quality for getting them patented. Initially this PE-analysis was nevertheless hard to decipher from eclecticists' points of view. But now, due to these 2 CRISPRETCI specifications, the necessity of the Supreme Court's SPL-framework-definition is — because of its indispensable implications, e.g. notional refinement — evident for securing the US NPS.

.b For stimulating mrat=ratpatenting of BIOETCIs (see Section V), the authors will soon provide of the above notions more concise rewordings in mratBIOIDL[6.c)]. I.e., their notional and syntactical semantics hence will be mathematically definable — in a second step.[1.c)]

**II.2 $^{BIO}$ETCIs' KRs are Negligent:** Besides the notorious misinterpretation of the framework[503], 2 bullet points identify different causes of the currently negligent KR of any $^{CRISPR}$ETCI: ●Overstretching the English in $^{CRISPR}$ETCIs' wordings, just as ●applying a wording practice contradicting 35 USC § 112 (see Section IV):

- **Grammatical and stylistic misfits:** The independent $^{CRISPR}$claims' use of the English grammar is often very unusual. E.g.: In the UC-$^{CRISPR}$ETCI[2.a)] its first sentence comprises a verb[(α)] and puts its substantive to a place[(α)], where it usually — here wrongly — must be interpreted as belonging to its preceding pronoun. Or: In the Broad-$^{CRISPR}$ETCI[2.b)] continuing its first sentence behind the verb 'introducing into'[(β)] far away at the place[(β)] with the 'an', which usually — here wrongly — must be interpreted as standing behind a by typo lost 'comma', which would make the following CRISPR-Cas being the preceding 'gene product'.[4.a)] I.e.: Both these erroneous interpretations are grammatically induced, not excluded!

  This may be seen from a different point of view: While, for $^{DNA}$ETCIs, the very elaborated patent specifications before their claims' sections are quite usual scientific presentations, their compressed claims' wordings are often unnaturally stilted, as is the case with the 2 above $^{CRISPR}$ETCIs (as just criticized) — thus dramatically reducing their broad comprehensibility. Even worse: This straightforwardly leads into misinterpreting the message that this compact wording should convey at a first glance.

- **Elucidations in the wordings of ETCIs[b)]:** 35 USC § 112 requires a patent specification to contain a written ETCI description "*in clear, concise, and exact terms*" — "*and shall conclude with one or more claims ... distinctly claiming … the invention*". This implies that such claims must not contain an ETCI's elucidation, as this then had to be interpreted as part of the invention — what this elucidation is not (but just part of its explanation). Moreover, for inventions of a cutting edge technology — e.g. CRISPR in DNA-technology — such distinctions are hardly recognizable and thus contradict its clear/concise/exact requirement. Evidently, the UC-$^{CRISPR}$ETCI just as the Broad-$^{CRISPR}$ETCI contain several such elucidations.

**II.3 $^{BIO}$ETCIs' KRs are Framework-Ignoring:** This is a key issue in patenting $^{CRISPR}$ETCIs, while the preceding sections were dealing with their semantics/pragmatics/semiotics[489ftn2.a)]. Part I stated to this end: "… *that each of these two $^{CRISPR}$ETCIs' current meanings doesn't own two properties indispensable for its being PE: A) ... and B) the second ETCI-property lacking is that it does not comprise – … – an application that transforms this $^{CRISPR}$ETCI to PE.*"

By stereotypically using the BRI for claim interpretation, this meaning of "*application*" has hitherto been broadly analyzed legally erroneously, leading into the known confusion about PE. This hitherto missing consensual meaning of the term "*application*"[500] — by *Phillips* to be determined much more thoughtfully than by the BRI[c)] — enforces awareness of the framework's indispensability for defining PE- and SPL-satisfaction & its true robustness.

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[4] **.a** The same negligence as to the stylistic use of natural English in claims' wordings holds also for its punctuation, backward-referencing, possessive pronouns, ….

**.b** — except for its introductory remark that summarizes the meaning of the ETCI —

**.c** The USPTO's 'old' claim interpretation, the "**Broadest Reasonable Interpretation**, **BRI**", insinuated for an ETCI's patent(-application) a for inventors and investors disastrous PE-deficiency, fortunately untrue[500]: That an ETCI can only be determined PE if it is BRI interpreted. By its pertinacious repeating this untruth, it practically barred the established SPL-experts from finding the PE-solution, as the BRI totally ignored the key PE feature(s) **A** and **B** (see II.3 above) – as the Supreme Court asked for it[500] and it is by the PE-analysis in *Alice* explicitly outlined![500].

The USPTO has recently induced — after all the permanent public complaints about BRI's many misleadings in claim interpretations[500], by its eventually having changed over to the "*Phillips*" claim interpretation[482], as of[500] — the key cognition: That clarifying **A** (and **B**) is crucial for consensually ending the PE-dilemma. This clear 'de novo' interpretation of the terms '*application*' and '**inventive** $^{Alice}$**concept**" on page 7 in *Alice's* PE-analysis mandatorily leads to these terms' meanings consistent to the Supreme Court's pertinent elaborations in ●*Mayo* and ●*Myriad*'s final pages: This very wide interpretation of the framework's key term '*application*', as refined by the Supreme Court in its *Alice* decision, namely ideally complements the notion of '*inventive concept*' — for clarity here called "**inventive** $^{Alice}$*concept*"[500]. It indeed eliminates the by the Supreme Court in *Bilski/Mayo/Myriad* clearly identified big problem of ETCIs' patenting — that their totally preemptive ones threaten the entire US NPS — and amazingly achieves this by minimal invasivity into it[480].

For an ETCI, its embedded $^{n}$PE invention 'TT0' and its "*application*"[500], often several to the latter belonging set of "**inventive** $^{Alice}$*concept***s**, **yS**" can be determined, here called "**ETCI's application potential**'. Both $^{CRISPR}$ETCIs patents show: Any such y may identify not only a single "**primary**" application belonging to y, but a set of "**secondary**" applications belonging to it or to any one of these additional inventive $^{Alice}$concepts. And during developing and drafting this ETCI this can be leveraged on by its inventor and/or investor.

Andrei Iancu's claim interpretation thus leads to a consensual termination of the § 101 dilemma[500] — eventually in line with the Supreme Court's requirements[503].

**.d** The 'framework' refinement of 35 USC/SPL by the Supreme Court — explicitly authorized by the US Constitution — has a long time commonly known and famous analogon in any art, especially in music, especially in jazz: Practicing it is often based on the choir/orchestra/…./band/group performing it (here the Supreme Court) sharing a common theme (here: 35 USC/SPL). Thereby the members of this choir/orchestra/…./band/group (i.e. its soloists, here is Justices) elaborate on this common theme by its reinterpretation while being accompanied and supported by this body (here Court). Any audience encountering a performance of this kind would usually be split into fractions, appreciating it or not — according to this fraction's preferred cultural paradigm in this specific art, hence liking or disliking this body's actual specific paradigm.

In case of the Supreme Court's decisions, they hold for any US citizen, no matter how (un)popular they are. Its framework refinement of 35 USC/SPL was originally not welcome, but the USPTO and a growing part of investors and inventors increasingly recognize its advantages & appreciate it.

## SECTION III. AI Stimulates Using the Broadly Known 'IT System Specification Technique'.[5.a)]

Section III requires that BIOETCIs are specified in '**natural English**' by BIOIDL[b)] (IDL = 'Innovation Definition Language')[372], as outlined in the below 3 boxes[c)]. IDL's principles are based on the roots of today's philosophy of IT System Design[2], the sole such philosophy since the 70s — as since then internationally extremely successful, thus eliminating all competing specification techniques. BIOIDL is IDL's adjustment to BIOtech needs[b)].

Section III indicates that using this IT System Design specification technique also in BIOtech is very advantageous: It facilitates recognizing a BIOETCI's ●notional & structural deficiencies in determining its BIOrelations and hence avoiding therein factual and/or legal errors[c)], just as the ●its total simplification in patenting it — to solely assessing its correct claim interpretation — stated by the '**BIOETCI-Patenting-Theorem**'[6.c)] of Section V.

The below 3 boxes for *UC*- & *Broad*-CRISPRETCIs and a *Myriad*-DNAETCI show of their 'BIOIDL-$^{struc}$KR[c)] specifications that their human comprehension ought to be supported by a graphical KR[c)]. Yet, this is postponed to[503] as it ought to visualize also synchronization needs of a BIOETCI's nonsequential algorithm (e.g. for a U/N-relation[8.c)]) and its active & passive context impacts. These are only very briefly touched in this PART III.

*Myriad*-DNA**ETCI**$^{1/7}$ in DNA-IDLKR$^{rat}$ has **N::= 2+2** ETCI-elements: **X1::=** Tissue_of_testee (TT), **X2::=** Wildtype-info (WT), **X3::=** Detector&Indicator of alteration of a BRCA1 gene (DEIN), **X4::=** Application (APP). The **K::=8+2** properties of ETCI$^{1/7}$ — put in DNAIDL — are: **EcrC0S::= {**

**(e1,1 =)e1::=** $^{T(issue_of_)T(estee)}$GS(equence)o(f)B(RCA)1g(ene), **(e1,2 =)e2::=** $^{TT}$GSoB1R, **(e1,3 =)e3::=** $^{TT}$GSoB1c;
**(e2,1 =)e4::=** $^{WT}$GSoB1g, **(e2,2 =)e5::=** $^{WT}$GSoB1R, **(e2,3=)e6::=** $^{WT}$GSoB1c;
**(e3,1=)e7::= diff**(e1,e4) **v diff**(e2,e5) **v diff**(e3,e6)≠Φ;

**[(e3,2=)$^{7}$e8$^{7}$::=** APP; **(e4,1=)$^{7}$e9$^{7}$::=** ∃ **allele** ($^{TT}$GSoB1g∈$^{hybrid(probe}$GSoB1g **&** $^{isol}$gDNA⊂$^{TT}$GSoB1g)), **(e4,2=)$^{7}$e10$^{7}$::=** e1;
**E3Pred$^{1/7}$::=**e9$^{7}$**]}.** — meaning: *Myriad*-DNA**ETCI**$^{1/7}$ is PE/$^{n}$PE iff **E3Pred$^{1/7}$**=T/F.

*UC*-CRISPR**ETCI**$^{1/X}$ in CRISPR-IDLKR$^{rat}$ has **N::= 7+2** ETCI-elements: **X1::=** a targeted DNA molecule (TDDNA-M), **X2::=** a target sequence (TSE), **X3::=** a complex (COM), **X4::=** a Cas9p (Cas9p), **X5::=** a DNA-targeting RNA (TGRNA), **X6::=** an activator RNA (ARNA), **X7::=** a targeter RNA (TRRNA), **X8::=** Detector&Indicator (DEIN), **X9::=** Application (APP, tbd)[500] with **K::= 16+2** E-properties: **EcrC0S::= {**

**(e1,1 =)e1::= is outside of bact.&archae. cell cont. by** COM, **(e1,2 =)e2::= comprising** TSE; **(e2,1=)e3::= hywi** TRRNA;
**(e3,1=)e4::= comprising** Cas9p, **(e3,2 =)e5::= comprising** TGRNA;
**(e4,1=)e6::=** X4;
**(e5,1 =)e7::= comprising** ARNA, **(e5,2 =)e8::= comprising** TRRNA;
**(e6,1=)e9::= hywi** TRRNA **to form a** dsRNA **duplex of a protein-binding seg.**, **(e6,2 =)e10::= hywi** TRRNA **to form a total of** 10-15 **bp**;
**(e7,1 =)e11::=** X2 , **(e7,2 =)e12::=** X6, **(e7,3 =)e13::=** X6, **(e7,4 =)e14::=** X5;

**[(e8,1=)$^{1}$e15$^{1}$ ::= F**, **(e8,2=)$^{x}$e16$^{x}$ ::=** APP; **(e9,1=)$^{x}$e17$^{x}$::= tbd, (e9,2=)$^{x}$e18$^{x}$::= e1**;
**E8$^{x}$Pred$^{1/x}$::=** (e15$^{1}$∨e16$^{x}$)**]}.** — meaning: *UC*-CRISPRETCI$^{1/x}$ is PE/$^{n}$PE iff **E8Pred$^{1/x}$**=T/F.

*Broad*-CRISPR**ETCI**$^{1/Y}$ in CRISPR-IDLKR$^{rat}$ has **N::= 12+1** ETCI-elements: **X1::=** a eukaryotic cell (EUC), **X2::=** a targeted DNA molecule (TDDNA-M), **X3::=** a target sequence (TSE), **X4::=** 1-or-several vectors (1os VEC), **X5::=** 1. regulatory element (REE1), **X6::=** 1 or several nucleotide sequences (1os NUS), **X7::= CRISPR**-Cas system (CR-CasS), **X8::=** guide RNA (guRNA), **X9::=** REE2, **X10::=** 1NUS, **X11::=** Type-II-Cas9 protein (T-II-Cas9p), **X12::=** Detector&Indicator (DEIN), **X13::=** application (APP-tbd)[500] – with **K::=17+2** E-properties: **EcrC0S::= {**

**(e1,1 =)e1::= containing & expressing** a TDDNA-M;
**(e2,1 =)e2::= comprising** a TSE, **(e2,2 =)e3::= encoding** the gene product; **(e3,1 =) e4:=** X3;
**(e4,1 =)e5::= com.** an REE1 **operable-in** ('**opi**') a EUC **operably-linked-to** ('**oli**') 1os NUS **encoding** a guRNA **hywi** the TSE,
**(e4,2 =)e6::= comprising** an REE2 **opi** a EUC **oli** 1 NUS **encoding** a T-II-Cas9p;
**(e5,1 =)e7::= opi** a EUC **oli** 1os NUS; **(e6,1 =)e8 ::= encoding** a guRNA;
**(e7,1 =)e9 ::= comprising** 1os VEC; **(e7,2 =)e10 ::= introduced** into EUC; **(e8,1 =)e11 ::= targets** the TSE, **(e8,2 =)e12 ::= hywi** the TSE;
**(e9,1 =)e13::= opi** a EUC **oli** 1 NUS; **(e10,1 =)e14::= encoding** a T-II-Cas9p; **(e11,1 =)e15::= cleaves** the TDDNA-M;

**[(e12,1=)$^{1}$e16$^{1}$ ::= F**, **(e12,2=)$^{y}$e17$^{y}$ ::=** APP; **(e13,1=)$^{y}$e18$^{y}$ ::=** tbd, **(e13,2=)$^{y}$e19$^{y}$::= e1**;
**E12Pred$^{1/y}$::=** (e16$^{1}$∨e17$^{y}$)**]}.** — meaning: *Broad*-CRISPRETCI$^{1/y}$ is PE/$^{n}$PE iff **Pred$^{1/y}$**=T/F.

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[5] **.a** Introducing into BIOtech the use of '**BIOSystem Design**, **BIOSD**' specification technique — for by 'separation of concerns' and 'semantical layering' decomplexing sophistication of algorithms (as done in IT System Design) and enabling automating them[182] — adjusted to the needs of the BIOcommunity, e.g. BIOIDL, would overcome its today total unawareness of the exactness & flexibility requirement coming with the (non)sequential[503]) algorithmic thinking about a BIOETCI and its and its modules' functional properties. This international BIOSD-uniformity also enables internationally grasping/checking/drafting patents on truly robust BIOETCIs.

**.b** BIOIDL is the BIOextension of the IDL-/SPL-/framework-subset of natural English — being an object language'[371] for drafting/stating 'BIOdomain-specific mratvratspecifications. In the above 3 boxes, a BIOtech-term of today's 'mratBIOflavor' of IDL is printed in bold if it is output by the "**Innovation Expert System**, **IES**" to its user, and printed normally if it is input to the IES by its user.

**.c** The boxes don't show the 3 BIOETCIs but their "**BIOstructures**"[6.c)] in BIOIDL. A BIOETCI in BIOIDL is read as natural English[2.a)/.b)], yet without any one of the problems addressed in Section II, complained about in[503]. On the other hand, once familiar with the BIOstructure one recognizes its simplicity, in spite of its exactness. The BIOstructure of a BIOETCI looks only complex, but this is false — and it is highly redundant to BIOETCI's graphKR, thus rendering both trivial.

**.d NOTE:** The BIOSD and its BIOstructure of a BIOETCI can evidently be interpreted as its test for having an mratBIOKR, i.e. as the "mratBIOETCI"-test — explained in more detail in[503] — here indicated by the boxes' bottom lines.

The Supreme Court requires in *Mayo/Myriad/Alice* that any ETCI[b], for being PE, applies the same philosophy that these 3 decisions indicate — structurally explicitly stated in the PE specification in its *Alice*'s opinion on page 7. Also the above $^{mratBIO}$IDL-specifications of the $^{DNA}$*Myriad-*/$^{CRISPR}$*UC-*/$^{CRISPR}$*Broad-ETCIs* show this specific '**use-** alias **need-**, **U/N-**,**structure**'[503], fictionally so construed — as otherwise they would contradict the Supreme Court's framework[b], i.e. would be legally erroneous. For this structure, the

"$^{ratBIO}$**ETCI patenting lemma** says**:** *A $^{ratBIO/PE}$ETCI implies it passes the $^{rat}$PE-Test*."

Before proving its holding, it must be determined what the term '$^{ratBIO/PE}$ETCI' means. A PE $^{ratBIO}$ETCI is by *Alice* defined as a pair <$^{nPE}$TT0, APP> of ●an $^{nPErat}$TT0, being **1.)**an invention, and ●an APP, being **2.)**a $^{rat}$application of this TT0 (i.e. "**using/needing**, **'U/N'**, **TT0**"[503]), and being **3.)**transforming the nature of this TT0 (i.e. not expanding the domain of an EcrC needed for completely defining it nor increasing these $^{rat}$EcrCs' minimal number, here called "**conservative**"), and being **4.)**together with TT0 significantly more than TT0 alone[c] (i.e. comprises a $^{rat}$EcrC basically $^{rat}$independent of TT0[c]). Moreover holds w.l.o.g.: **5.)**∀ $^{rat}$EcrCs are basically $^{rat}$independent.

**Proof:** It shows that from these 5 $^{rat}$ETCI-properties follows its being truly $^{ratPE}$robust, as a $^{ratBIO/PE}$ETCI passes the 7 $^{rat}$PE-FSTP-testo in SECTION V. Indeed holds: **1.)&2.)**implies by[b] passing FSTP-test1)-4), **3.)**implies passing test5), **4.)**implies passing test6), and **5.)**implies passing test7). **q.e.d.**

Intermediary summary: In patenting $^{BIO}$ETCIs, there are still 3 classes of notional problems to be solved:

- While the 'Section-II-notional-deficiencies' of $^{BIO}$notions caused the CAFC's/USPTO's/PTAB's disastrous statistics[6.a], $^{BIO}$problems of this first kind are **straight-forward fixable**[a], in principle at least: By creating consensus about any one of them is an efficient and resilient way to resolution of any such problem.
- The #2 kind of $^{BIO}$problem is **much more difficult**: It is the § 101 debacle, caused by the patent community's initial adversity against the Supreme Court's 'SPL-paradigm-refinement' implied by its framework's PE-analysis in *Alice*. For overcoming this problem a consensus, as in a #1-problem, is not sufficient: As ETCIs got socioeconomic key issues, the Supreme Court stated a fundamental truth inherent to ETCIs[b] — univocally & grossly misinterpreted[459, 480] by the CAFC/USPTO/PTAB, all other courts, and all the patent community, thus excluding predictability in SPL precedents about ETCIs and lasting for years. It is now coming to its end by[7.a)/§101].
- The #3 kind comprises the **worst** $^{BIO}$ETCI-**problems**. It is based on fundamental knowledge gaps in $^{BIO}$tech as well as in patenting. Hitherto these are nowhere as such clearly criticized — although concerning long time established knowledge, i.e. about ●nonsequential algorithms (in $^{BIO}$tech) and as to ●§112 (in SPL). For clarity, these #3-problems are isolated from the #1-&#2-ones and briefly outlined in Section IV, next.

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[6] **.a** comprising their rejections of patent applications and revocations of patents granted already.
Compared to[489], the $^{mratBIO}$notation for a $^{BIO}$ETCI's specification has been changed. Thereby misunderstandings of these 3 $^{BIO}$ETCIs may still prevail, as not yet approved by their inventors — though by *Biosig* their views may eventually be decisive, especially as long as in $^{BIO}$tech no poposc exists yet, as shown by its absence from any pertinent ordinary textbook (not research reports, being of no such 'standard determining' competence[7.a)/§112]).

**.b** — embedding an $^{nPE}$invention (which is a totally preemptive TT0 under SPL, which therefore ●comprises a nonempty set of exceptional crCs, 'xcrCS' and preempts any application of TT0, both by definition of $^{n}$PE and ●passes due to SPL the FSTP-test1)-3), as if it failed to pass one of them there would be no definition of an invention under SPL, contradicting the precondition), which thus guarantees that the $^{BIO}$ETCI, being a such application, also passes FSTP-test1)-3), whereby this $^{BIO}$ETCI-application is not totally preemptive, because of FSTP-test6 (see also[c]) —

**.c** For an ETCI embedding a TT0 with a '$^{BIO}$molecule' (i.e. with xcrCS≠Φ) this ETCI-use-/need-structure is by whatever fictional APP construable, thus meeting this structural requirement, then being called "$^{BIO}$**ETCI**", having a KR "$^{(mphys...mat,graph)BIO}$**KR**" and a structure called "$^{BIO}$**structure**".
The latter is defined as E-crC0S$^{mrat}$ **::=**{E-inC0k ∨ E-ninC0k,1≤k≤K} ⊂ COM($^{BIO}$ETCI) (see the prologue of any ETCI's general 'claim interpretation, CI' definition, which for a $^{BIO}$ETCI's CI additionally comprises the knowledge that this ETCI is $^{BIO}$structured[6.c)] in $^{graph\#BIO}$KR — as shown&arranged&explained rudimentarily on page 8 and completely in[503] and on p11) in FSTP-test6' denoted by "U/N"— whereby (E-crCS$^{TT0}$⋂(E-crCS$^{ETCI}$\E-crCS$^{TT0}$)=Φ) ∧ (∃E-crC$^{1/2}$∈E-crCS$^{ETCI}$\E-crCS$^{TT0}$**:** (E-crC$^{1/2}$ is (basically independent over) | (U/N) E-crCS$^{TT0}$)).
Of a $^{ratBIO}$ETCI is principally known — by definition of "rat" — how to proceed for mapping (by a "$^{ratBIO}$**M**") its components onto its $^{matBIO}$ETCI. Of the same wording's $^{mratBIO}$ETCI (its meaning is mathematically not yet defined but mentally clearly the same as in the $^{ratBIO}$case, due to Biology's strongly limited flexibility) would — by definition of "mrat" — only be known that it is in principle rationalizable (and hence mathematizable) but not yet how. Thereby any $^{BIO}$ETCI has the property that in its FSTP-test1 ∀E-inC0n∈TT0 & E-inC0N holds O-inC0n = E-inC0n and the remaining O-inC0n's conjunction is a compound concept. From $^{ratBIO}$M$^{-1}$ one recognizes that necessarily holds[503] $^{mratBIO}$**M** ≡ $^{ratBIO}$**M**, as this isomorphism[5] may be confirmed by a contradiction proof and[8.b)]. Additionally, otherwise also the above empirical confirmation is flawed.

## SECTION IV. Serious Errors of Any Today's (Non)Granted Patent on "almost-mratBIOETCIs".

The Sections II & III required clarifications of BIOETCI-deficiencies achievable more or less straightforward. By contrast, this section indicates that & why — even if all there identified deficiencies would never had existed — any hitherto BIOpatent(application) teeters on the brink of the abyss of annihilation[7.a)].

There are at least 4 such 'ko threats' in seemingly any BIOETCI-patent: ●Legally, it does not meet **1.)** its usefulness requirement stated by § 101 and **2.)** the enablement requirement stated by § 112. ●Factually, it ignores **3.)** that it is vastly based on non-sequential algorithms and **4.)** the Supreme Court by its framework implicitly requires a notional refinement of the BIOETCI's properties. All 4 threats — next briefly indicated in telegram style[a)], in[503] in more detail — are tightly related to BIOETCIs' unavoidable off-target mutations.

**Ad 1.):** As to the **usefulness requirement of § 101** the Section III has already clarified that probably none of today's BIOETCIs provides any quantified guarantee for the nonoccurrence of any off-target mutation during applying it — at least as coming with most advanced but everyday drugs' instruction sheets, although the risks encountered from advanced BIOETCIs usually is much more serious than these drugs' threats. It seems that advanced basic research always focuses — due to evident reasons — on developing hope creating progress, instead of integrating into the development strategy for the eventual ready-to-go BIOproduct unavoidable quality checks&reports.

**Ad 2.):** As to the **enablement requirement of § 112**: It is just incredible that BIOETCIs have often been granted to patents in spite of their specifications not disclosing for the poposc[7.b)] textbook-level information enabling her/him to reproduce this BIOETCI. Instead this concise information — for reproducing on the mental textbook level specifically this BIOETCI and its quality assessing information — is replaced by a flood of information for a highly scholarly person capable of grasping a broad report on evolving BIOtech researches, but not yet to be found in a textbook on BIOtech and describing other than the BIOETCI's specific reproducing information.

**Ad 3.):** Molecular Biology literature has recognized that loops in DNAETCIs may cause feed-back effects, hence deal with nonsequential algorithms, this research is nondeterministic and hence for our analysis useless. Nevertheless, they are constitutive for CRISPRETCIs, ZIFNETCIs, TALENETCIs, and alike. Not considering their synchronization needs when engineering such ETCIs ●on the one hand inevitably cause at-target and/or off-target mutation faults[503] and, ●on the other hand, this means not theoretically and/or practically investigating whether BIOtech would permit other and more beneficial (especially more reliable) synchronization methods than the known ones.

**Ad 4.):** The framework-implied KR-refinement of ETCI's has in FSTP technology been constitutive for its KR's O/A/E-layering — as known from it and IT System Design. By contrast, neither the BIOtech- nor the patenting-community is familiar with it, which disables both from systematic 'decomplexing of problems', e.g. in BIOETCI.

The USPTO's new director managed to create hope, in spite of this frightening amount of work. Andrei Iancu strives for reestablishing the worldwide leading role of US innovativity in all emerging technology areas — just as the Supreme Court implicitly did in wake of its defining the SPL-framework. I.e., he tightly and unmistakably joins the Supreme Court's *KSR-/…-/Alice*-view about what is necessitated by securing the US society's wealth.

In his striving for successfully passing this challenge, a chain of his appropriate decisions as to the USPTO's examination of patent applications is indispensable for taking the USPTO to this by the US Constitution implicitly identified target. His first decision, stopping the BRI-nonsense, has been to the point. Two more of his decisions — settling the §101-problem and starting leveraging on AI's key potentials (including[468,477]) — are evidently on the way for this year 2019. The earlier resp. just outlined searching- and §112-parts-problems are thereafter by enough good-will also solvable. The above remaining 3 heavy-weight problems are thereafter by good-will alone not solvable, as here much more hard work in SPL-R&D is indispensable, first. This in total means: If he and his USPTO would succeed along this line, they would unleash huge US innovativity potentials.

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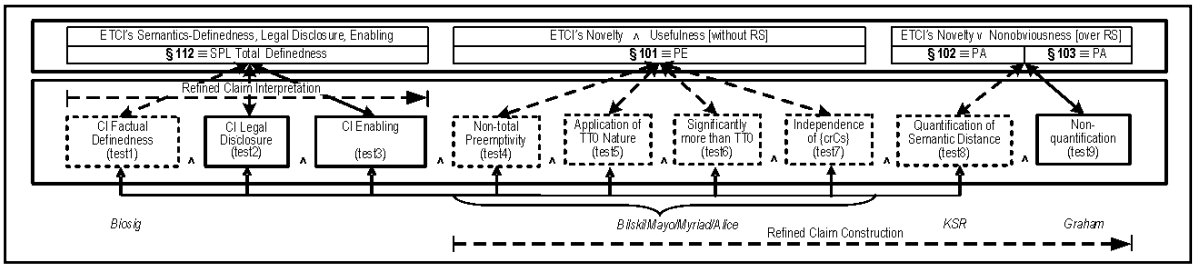
[7].a A remark upfront: The size of the BIOproblem addressed here is so huge that this mailing still refrains from any suggestion how to deal with it. Of the USPTO's 2019-guidelines[505] as to §§ 101/112, ●the first one is finally approaching completeness, yet notionally still put metaphysically and hence leave room for questioning — already happening[508] — its exact meaning, as scientifically unquestionably identified by FSTP technology as implied by the Supreme Court's framework, while ●the second one is still in its 'notional early infancy' and hence incomplete[8.f)].

.b cont'd from[1.b)]: … **BIO** 'BIOtech'; **RS**$^{SD}$ the '**semantic distance**, **SD**' between the ETCI at issue and the given '**reference set**, **RS**' of pertinent prior art & ordinary skill documents; **COM(ETCI)** the '**combination of ETCI-elements** of this ETCI.' Thereby a KR-quality index may be pre- or postfixed to the BIOIDL-term that is qualified by it, also distributed as shown in[1.c)].

## SECTION V. AI Enables Recognizing: Any $^{mrat BIO}$ETCI is a priori Truly $^{rat}$Robust.

As shown below, AI maps ∀SPL requirements onto ∀ETCIs — for testing their ETCI-elements' properties under SPL.




**Legend:** AI models the mapping of 35 USC/SPL's onto FSTP-Test's $^{mrat}$semantics by the arrows between the inner boxes within the upper/lower boxes — showing SPL's pre-/post-framewok meanings by solid/dashed lines. Thereby, the Supreme Court's post-framework SPL semantics only notionally refines its pre-framework semantics, thus establishing consistency in future patent precedents — impossible to define in pre-framework (= 'classic') SPL semantics, just as in its CAFC's & USPTO's marginal adjustment to the 6 Supreme Court refinement requirements. Their ignoring 5½ refinements evidently leaves SPL inconsistent, even metaphysical.

Thereby AI recognizes the Supreme Court's in total 9 refinements of the 3 paradigms, being 3 '**basic compound socioeconomical concerns**' to be met by ETCIs for patent protection. An ETCI's SPL-satisfaction test hence assesses ●the conjunction of all requirements implied by the 4 §§ of 35 USC/SPL, by its basically independent properties, for being patented — i.e. its being **'factually(complete∧correct)∧legally(definite∧disclosed)∧enabling' properties by §112 required**, **'patent-eligible, PE' by §101**, & **'patentable, PA' by §102/103**) — and maps this test to ●an equivalent conjunction of this ETCI's inventive concepts modelling its ETCI-elements' properties. Yet: While originally ETCI's O-concepts are compound (i.e. $^{mphysvmrat}$ones), the framework indispensably requires elementary $^{mrat}$E-concepts to model ∀ properties of ∀ Xn's, 1≤n≤N (see the PE-Test).

This box hence visualizes AI's mission in patenting ETCIs. This indispensably requires a deterministic AI. It enables modelling any $^{mrat}$ETCI as a mathematical theorem, of which the FSTP-Test mathematically proves its correctness iff an ETCI satisfies SPL. I.e. AI consequently shows: SPL is an exact science.

This mapping of $\forall^{BIO}$ETCI scientifically implies the below patenting-theorem — hitherto felt impossible[c].

**The $^{BIO}$ETCI patenting theorem:** Any $^{mratBIO}$ETCI is a priori $^{rat}$robust ●PE and ●PA over an $^{mrat}RS^{SD}\geq 2$.

This is a huge practical advantage of any $^{mratBIO}$ETCI. For mathematically proving its ●PE, it suffices showing its empirical $^{mratBIO}$CI passes test1)-3)[e], and its ●PA (= it $^{rat}$satisfies SPL) for a given RS, if it passes test8)-9), too. I.e.: $^{mratBIO}$ETCI's sophisticated test4)-7) are obsolete and need not be tested or understood by a tester[d].

**metarational claim interpretation (CI) :** <**external input::= $^{mratBIO}$CI, internal output ::= COM($^{mratBIO}$ETCI)**> & begin:
Definition of $^{nPE}$TT0 & COM(ETCI)::= {O-crC0n ::= $^{mphys}$O-MUIS0n,1≤n≤N, thereby identifying TT0} ∪
∪ {A-crC0n, 1≤n≤N} ..... superfluous for $^{BIO}$ETCIs[488] ..... } ∪
∪ {E-crC0S$^{mrat}$ ::={E-inC0k ∨ E-ninC0k ::= k-$^{BIO}$*IDL-sentences*, disclosed by E-$^{mrat}$MUIS0k,1≤k≤K}.
**1)** if [COM(ETCI) is legally&factually E-complete∧-correct∧-definite∧(O-inC0n=∧$^{1\leq k\leq Kn}$(E-inC0nk∨E-ninC0nk),∀1≤n≤N))∧$\Sigma^{1\leq n\leq N}$Kn=K] then go on;
**2)** if [{O-inC0n, E-inC0nk) | ∀1≤n≤N ∧ 1≤k≤Kn} are lawfully_disclosed] then go on;
**3)** if [O-crC0n is enablingly disclosed, ∀1≤n≤N] then output COM($^{mratBIO}$ETCI) & stop.

**rational claim construction (CC):** <**internal input::= COM($^{mratBIO}$ETCI), external output ::= COM($^{ratBIO}$ETCI)**> & begin:
**4)** if [COM(ETCI)$^{mrat}$ comprises an $^{n}$PE TT0] then go on;
**5)** if [COM(ETCI)$^{mrat}$ is an application of TT0's nature] then go on;
**6)** if [COM(ETCI)$^{mrat}$ is significantly more than TT0] then go on;
**7)** if [COM(ETCI)$^{mrat}$ comprises only basically independent E-inC0nk] then [input COM(RS) $^{mrat}\equiv$ O-/A-/E-inCnS, 1≤n≤N;
**8)** if [COM(ETCI) $^{mrat}$ has a definable A/N-Matrix over RS] then go on;
**9)** if [COM(ETCI) $^{mrat}$ has sem. height(RS ≥1/≥2 if $AC^{1/\geq 2}\in$RS)] then output 'COM(ETCI)$^{rat}$ is PE' & stop.

**mathematical claim construction (CC):** <**internal input::= COM($^{mratBIO}$ETCI), external output ::= COM($^{matBIO}$ETCI)**> & begin:
**4')** if [xcrCS ≠ Φ] then go on; [6.b]
**5')** if [$\prod^{TT0}$scope(E-crCS$^{ETCI}$) ⊂ ∏ (E-crCS$^{TT0}$)] then go on;
**6')** if [{E-crCS$^{ETCI}$\E-crCS$^{TT0}$} U/N E-crCS$^{TT0}$)] then go on; [6.c]
**7')** if [∀ϵ{E-crC0nk | 1≤n≤N ∧ 1≤k≤K$^{n}$} are basically independent of each other] then [input COM(RS) $^{mrat}\equiv$ O-/A-/E-inCnS, 1≤n≤N];
**8')** if [$\forall^{i,n,k}\exists\Delta^{i,n,k}$ ::= if (E-crCink = E-crC0nk) 'A' else 'N'] then go on;
**9')** if [$\sum^{1\leq n\leq N}$(min$^{\forall i\in[1,l]}$|{<$\Delta^{i,n,1}$="N", ...., $\Delta^{i,n,Kn}$="N">}|)≥2] then output 'COM(ETCI)$^{mat}$ is PE' & stop.

Finally: In[503] both guidelines[7.a] will be elaborated on in the light of this mail, evidencing: Andrei Iancu's solving the USPTO's problems is — legitimately, and for consistence reasons also necessarily — based on their AI-supported scientification[f]. In the current §101-guideline, this is presented not yet quite to the point, but on this eventual occurrence it will for the USPTO be a big step forward, a quantum leap, induced by the Supreme Court's §101-framework. The also necessary §112-guideline needs steps even bigger and much harder to perform. Yet, as the SPL-satisfiable-problem is of FFOL, its §112 aspect is amenable to scientification, too. [8.a]

[8] **.a** As all 4 boxes are on 1 page — for facilitating grasping this $^{BIO}$theorem and its proof — their wordings must individually be zoomed into readability. cont'd p.12

## The FSTP-Project's Reference List (Version of 25.01.2019)

**Most of the FSTP-Project papers below are written in preparation of the textbook[182] – i.e. not fully self-explanatory independent of their predecessors.**


[2] The term 'Artificial Intelligence' here denotes specific cutting edge deterministic IT & Mathematics areas, e.g. in Knowledge Representation (KR)/ Description Logic (DL)/ Natural Language (NL)/ Semantics/ Semiotics/ (IT/Nonsequential) System Design/…, i.e. a resilient fundament for analyzing 35 USC/SPL by AI-based "Facts Screening/Transforming/Presenting, FSTP"-Technology, developed here, induced by the US Supreme Court's framework decisions.[182]
The Molecular Biology meanings of all 'BIO-prefixed' acronyms are based on so understood AI.

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[218] B. Russel: "Principles of Mathematics", see also Wikipedia.

[278] a.) D. Parnas: Personal Communications, Berlin, 1975.
b.) D. Parnas: "Software Fundamentals", ADDISON-WESLEY, 2001.

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[313] **a.)** Wikipedia: "First-order logic", **b.)** Wikipedia: "Prädikatenlogik", **c.)** Wikipedia: "Analytic Philosophy", **d.)** Wikipedia: "D. Parnas".

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[332] S. Schindler: "The Notion of Claiming in SPL – pre&post Aufklärung", p. 10.10.2016*)

[335] T. Kuhn: "The Structure of Scientific Revolutions", UCP, 1962, see also Wikipedia

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[349] B. Wegner:: Invited paper, "Robust Claim Interpretation and Claim Construction for an ETCI, - Steps of a "Mathematical Theory of Innovation"", Bangkok, ICMA-MU, 17.-19.12.2016*)

[353] S. Schindler: "The Lesson to be Learned from the US PE Hype:", publ. 11.12.2016*).
[354] S. Schindler: "An Amazing SPL Cogn.: Any Pat. Appli. is Draft. Tot. Rob.", publ. 31.01.2017*).
[355] S. Schindler: "An Ama. SPL Cogn.: Any Pat. Appli. is Draft. Tot. Rob.", pub.07.03.2017*).

[361] J. Straus: „IPRs and Bioeconomy", Journal of IP Law&Practice, 14.07.2017
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[406] S. Schindler: "The PE-Theorem, FSTP-Test, and the US Innovation Econo. … ', publ. 01.08.2017*)

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[468] S. Schindler: "Andrei Iancu's Further Pub. Discuss. about USPTO's Serv.", publ. 11.05.2018*)
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[482] S. Schindler: "Andrei Iancu — After 100+ Days Even Stronger on Track.", publ. 25.07.2018*)
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[509] tbd in [503]


*) ***documents and full list available at*** www.fstp-expert-system.com

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**cont'd**[of.p.11] The $^{mphys\vee mrat}$based map M — of $^{rat}$AI from $\{\forall^{mphysBIO}$ETCIs$\}$ X $\{\forall\in^{mrat}$SPL$\}$ into the $^{mphysBIO}$CI X $^{ratBio}$CC defined by the FSTP-Test, visualized in the top box and commented in its legend, changes map's KR[1.a)] — depending on map's execution state — from mphys to rat[f].

[8] **.b** $^{mphys}$KRs will probably disappear in patent business[6.a)]. The $^{mrat/rat/mat}$truth values of the conditions in the FSTP-testo's, 1≤o≤9, of an ETCI's PE-Test ⊂ FSTP-Test are invariant over these KRs[1.a)] related to each other by kind of 'coordinate system transformations', being isomorphisms[5] between them.

**.c** These crucial & very time consuming processes of patent business are, as hence of $^{mat/rat}$KR, vastly automatable[503]. This is good to know for the case that one does not trust the $^{BIO}$ETCI patenting theorem and/or its proof[e]. For socioeconomic impacts see[468].

**.d** By its '$^{mrat}$' precondition this theorem **is invalid** in SPL interpretation being ●framework-refined: $\forall^{mphys}$ETCIs and ∀ nonconservative ETCIs (esp. such $^{CII}$ETCIs), and ●classic: ∀ ETCIs anyway (as first SPL-refinement & hence mathematical Logic in SPL had to be induced by the Supreme Court's framework).
Vice versa, this theorem **is valid** — not only for $^{BIO}$ETCIs, but also — in framework-refined SPL interpretation ∀ conservative $^{CII}$ETCIs.

**.e** **Proof of the $^{BIO}$ETCI-patenting-theorem:** Due to the $^{ratBIO}$ETCI PE-lemma and[6.c)], this proof is now trivial, as $^{mratPEBIO}$ETCI = $^{ratPEBIO}$ETCI is a priori truly $^{ratPE}$robust (due to the lemma), and by test8)-9) => also absolutely $^{rat}$robust. **q.e.d.**

**.f** This closer look at them will show that the paradigm refinement of the SPL for ETCIs implied by the Supreme Court's framework is now implicitly performed also by the USPTO, due to the necessity to distinguish metaphysical from metarational KR-quality, already clearly recognizable in the § 101 guideline