The CAFC/USPTO Biotech/PE-Decisions Reconsidered — Especially for Biotech/R&D-Investors

Sigram Schindler
TU Berlin & TELES Patent Rights International GmbH
www.fstp-expert-system.com

I. The Supreme Court's ETCI-Framework Meets R&D-Investors' Needs — also for Biotech ETCIs.[1.a)]

This Section's title is proven correct in[354,355,415] by a scientifically clean — i.e. hardly to counter — rationale for its statement's truth. By contrast, most Biotech-/ⁿPE-decisions of the CAFC, District Court, and USPTO state the contrary[b)] — as most panels & surveys complain[426-435], implicitly asking for an urgent change.

Here it comes: Any such Biotech-ⁿPE-decision is obsolete! It contradicts the Supreme Court's framework[3.c)] precedents, *KSR/Bilski/Mayo/Myriad/Biosig/Alice,* by ignoring the 5 requirements they state, 4 ex- & 1 implicitly. They are to be met by any ETCI for being definite/patent-eligible/patentable, <u>and especially without threatening the NPS</u> — i.e. for satisfying 35 USC §§ 101/102/103/112 as interpreted by these 6 Supreme Court framework decisions.

These 5 Supreme Court requirements to this end are: An ETCI must be **1.)** considered as being made up by its incremental inventive element(s) alias '**inventive concept(s)**' (*Mayo/Myriad/Alice*), **2.)** precisely described by metarational and rational notions[415ftn3.d)] modeled by 'E-crCs'[415ftn3.c)], **3.)** claim interpreted by screening its whole specification for finding a correct interpretation of its wording (*Markman*, *Mayo*, *Biosig*, *Alice*), **4.)** claim interpreted as required by *Biosig* (not the BRI), and **5.)** of [limited]PRE (*Bilski, Mayo, Myriad, Alice*).

Of these 5 requirements the CAFC has hitherto not even noticed the 2nd and the 5th one. I.e.: Its 2-step PE-test contradicts the Supreme Court's 2-step PE-analysis (by *Alice* defined in detail[415]). But meeting this very PE-analysis is necessary and sufficient for achieving consistency , i.e. predictability, in testing Biotech-ETCIs for PE[415].

As to the above referred to CAFC's ⁿPE decisions: Any one of them is void, and its Biotech-ETCI is already PE if it only meets the requirements **2.)&5.)**. Their meeting the 3 remaining requirements is here assumed — as meeting them is straight ahead derivable from its specification.

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[1] **.a** This ANNEX to[415] is as brief as possible for conveying its message as of its title. All names & notions from[415] may hence be assumed to be known. Also quoting precise references to *KSR/Bilski/Mayo/Myriad/Biosig/Alice* and the USPTO's BRI is here superfluous (see[182]).
Moreover, the emphasis of this ANNEX on Biotech should not be over interpreted as meaning that the elaborations here do not hold for the IT area. The contrary applies: Most of the presentations here and in[415] belong to the know-how of any qualified System Design engineer[218], for 40+ years, when in System Design the same notional paradigm refinement occurred that is currently inevitably taking place in SPL precedents about ETCIs: In both areas for excluding inconsistencies — there in IT systems' runtime behavior, here in its analogon, the execution of SPL on ETCIs. Such inconsistencies are vastly intolerable in System Design just as in SPL, i.e. are crucial for their survival. They emerged by then due to the advent of IT systems of a complexity partly surmounting human comprehensibility — today due to the advent of ETCIs that from the outset are partly incomprehensible as fictional (hence necessarily based on models enabling eliminating fictions' risks).
Excluding inconsistencies requires in both cases correctness proofs of their objects, i.e. of a System Design-implementations resp. its analogon, an ETCI-specification. Today the former is only occasionally possible, the latter for any framework-based ETCI-specification.

.b then always based on an incomplete, i.e. false interpretation, of the Supreme Court's framework decisions, e.g. its PE-analysis in *Alice*[415].
These 5 false interpretations have a common trivial source: Notionally/Logically it is impossible that an ETCI's inventivity and/or scope and/or whatever is definable by 'limitations' of something usually unknown — for CTCIs often tolerable, for ETCIs not: Precisely specifying an ETCI in classical SPL (always practicing such absurd thinking) is pure Metaphysics alias Irrationality — though today being the normal case!
The reason for this absurd thinking with CTCIs being tolerable is that most of their properties are visible/tangible/nonfictional and hence intuitively comprehensible[a)] (except their scopes, as being fictional and hence in nonrefined SPL not precisely definable). By contrast, any ETCI — by its definition its properties comprise some fictionality, otherwise it were a CTCI[a)] — is precisely definable only by axiomatization the meaning of this fictionality, indispensably requiring an intuitively comprehensible "model"[410] providing an interpretation basis for this precise definition. Thus for an ETCI an increment of novel but nontransparent inventivity may be defined precisely by an 'exceptional inventive concept' on top of such a model — for a CTCI being superfluous as being transparent and then defined precisely by an 'ordinary inventive concept' without modeling nontransparancy. I.e., a CTCI/ETCI is by its definition described by novel 'element(s)' alias 'creative concept(s), crC(s)', of which none / at least 1 is exceptional.
Evidently, for some ETCIs denoting some of their crCs as 'limitations' is not a problem. E.g. in testing an ETCI for satisfying SPL's framework denoting its ordinary crCs as limitations does not create confusion, while denoting its exceptional crC(s) as limitation(s) creates inconsistencies[c)].

.c An incremental element of an ETCI's total inventivity often has in its specification the KR of an A-crC[415ftn3.c)], i.e. a conjunction of 1 or more ordinary and/or exceptional E-crCs. In IT System Design Technique[a)] it has been well known, since the 70s, that in an IT system the occurrence of an exceptional element — there called 'exceptional event' alias 'interrupt' — is notionally and by its implementation clearly to be distinguished from its 'exception/interrupt handler'. I.e., that an inconsistent system design often inevitably results from assuming that both notions[415ftn2.a)] need not be considered mutually independent. For ETCIs this necessity — as to avoiding inconsistencies in their SPL-precedents — holds also for considering mutually independent their natural phenomena and their handlers/markers.

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II. There is a Big Flaw in Most of Today's §101-Panels/-Surveys/-Decisions — yet not Discussed.[2.a)]

It is not painting with a broad brush when stating two aspects of today's state of SPL-precedents on ETCIs:

A) By its above 6 decisions, *KSR/…/Alice,* the Supreme Court increased and invited to further improve[3.c)] the quality of 35 USC/SPL on ETCIs to a level enabling the innovative potentials of the US economies to unfold such that they guarantee the wealth of US society — impossible[b)] if SPL precedents about ETCIs is unpredictable, i.e. nondeterministic, hence not trustworthy.[1.a)]

B) This in turn implies that SPL is no longer left a law just as any other, but is upgraded to guarantee absolutely robust US patents on ETCIs[c)]. This is evidently possible only if SPL and ETCIs are spotlessly cleanly mathematized, i.e. scientificated — which has been enabled by the Supreme Courts *MBA*-/ETCI-framework[3.c)].

A) addresses a Constitutional issue outlined by the Supreme Court's *Mayo* decision. **B)** defines/introduces a "**white knight**"[d)], by the Supreme Court implicitly generated by the 6 decisions *KSR/…/Alice*. The CAFC fails this white knight's premiss/paradigm[d)], as known from[415].

The rest of Section II briefly outlines a list of recent indications from panels, meetings, and/or individuals — mostly issued by them unintentionally but nevertheless unmistakably — of urgent interest in consolidating the currently for investors untenable '101-situation'.

+ The USPTO's §101/Biotech meeting in Alexandria on 02.08.2017**:** It rejected the CAFC's&USPTO's 2-step PE-test, see[415].
+ The FCBA-conference in London on 25.09.2017**:** E. Haug[430] and his panel about TRIPS and 35 USC/SPL outlined the need of an international consensus on innovations, especially on Biotech-ETCIs — requiring their clear D-/PE-/PA-tests.
+ The BIO's §101/Biotech-conference in Alexandria on 29.09.2017**:** Here, •L. Fischer[426] & J. Cohan [429] updated their §101/PE-summaries[414,413] and discussed the vagueness of the CAFC's&USPTO's 2-step PE-test. •H. Sauer[427] confirmed the untenability of the vagueness of the CAFC's&USPTO's 2-step PE-test and suggested refining it — by adjusting its preciseness to specific Biotech-ET-areas' needs[e)]. •W. Woessner stated a fundamental truth: An ETCI's being PE/ⁿPE is — by the PE-analysis of the Supreme Court's *Alice* decision — not at all depending on the kind of an ETCI's subject matter (in the CAFC's&USPTO's 2-step PE-test being key yet vague) but solely on this ETCI's structure of whatsoever kind of subject matter, as by the *Alice's* 2-step analysis[415] clearly determined (e.g. as implemented in the FSTP-Test[406]).
+ The private meeting with the CAFC's former chief judge P. Michel in Alexandria on 30.08.2017: As a broadly recognized opinion leader in the US patent community, he has insisted for a long time **1.)** in regaining consistency&predictability in SPL-precedents, about ETCIs too, hence **2.)** in excluding the USPTO's BRI from court decisions[f)], as the USPTO itself now also sees it[424], and **3.)** additionally qualifies for Biotech-ETCIs the vagueness of the USPTO's 2-step PE-test[415] as 'very high'.
+ The FCBA's §101/Biotech-conference on 04.10.2017 in New York — with a first panel[431] stating in its full breadth its incomprehension of how Biotech-R&D is allegedly supported by current SPL precedents. The second one[432] deserves Section III of its own.

The clear key consequences from carefully listening to all investors' voices here referred to: They all •complain of the CAFC's&USPTO's applying the BRI for claim interpretations and the inacceptable vagueness of their 2-step PE-test (both contradicting the Supreme Court's framework as of Section I &[415]), and •hope the Supreme Court eventually will establish a meaningful consistency of SPL-precedents on Biotech-ETCI patents by its framework'[3.f)]/*Alice*'s 2-step PE-analysis[415] (completely&correctly implemented by the FSTP-Test) .

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[2] **.a** This big flaw is indeed there — as proven in detail in[415] already.

.b — as this requires incentivizing to invest huge amounts of human and financial resources into the corresponding long-term/high-risk R&D efforts in all areas of life, especially in all kinds of biotechnologies —

.c The Supreme Court achieved this upgrade of the metaphysical 'mini-ontologies' of classical SPL & ETCIs' interpretation to their rational KR — by a tiny notional refinement of the interpretation of the 4 §§ 112/101/102/103 of 35 USC (which describe all ETCIs as notional creations all properties of which satisfy all 4 of the §§). This tiny notional refinement is evidently unavoidable for excluding that ETCIs would put into jeopardy the entire US NPS (as the Supreme Court repeatedly explained in its SPL-'framework').

.d The "white knight"-metaphor indicates that a CAFC's decision about an ETCI is depending on a strong premiss alias paradigm (being this white knight) that, if failing/failed — what is not questioned by it although being questionable — falsifies this statement. The here white knight is that the CAFC's&USPTO's 2-step PE-test is a correct & complete implementation of *Alice*'s PE-specification — being an indeed failing white knight[415].

.e FSTP-Technology enables — right from its outset[5] and facilitated by IDL[372] — the notional SPL-interpretation-refinements required by the Supreme Court for all ETCIs (see Section I, requirements **1.)-5.)**). On top of them ET-area-specific IDL-extensions, provided by 'ET-area-specific IDL-libraries' may vastly simplify drafting totally robust patents for such ET-area-specific ETCIs. The current complexity of ET-area-specific ETCIs — of IT- or Biotech-ETCIs — does not yet require such additional 'ET-area-specific' libs. Though, 'non-functional' libs may organizationally become important before.

.f as notionally indefinable, with its overboard going SPL relevant meaning determining — fine for claim interpretation in USPTO-internal examinations[425].

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III. The CAFC Panel Explicitly Denies such a White Knight in Its Current 101/Biotech-Decisions.[3.a)]

The just mentioned second panel of this FCBA meeting in New York on 04.10. is evidently[432] representing primarily the CAFC's position as to its 101/Biotech cases, being the main theme of this meeting. And all such CAFC cases are equally evidently based on the 'white knight'-paradigm/premiss[2.d)], common to them.

Moreover, this panel has all attributes legitimizing it to answer the fundamental question: How could/can the CAFC then so incompletely interpret the Supreme Court's *MBA*-framework, especially its *Alice*'s PE-analysis[415]? In spite of:

- its excellent judges (and those of other US courts, besides many other outstanding US patent experts)?[b)] and
- the Supreme Court repeatedly having invited/encouraged completing it, e.g. by[c)] and its framework's wording?[d)].

The panel's presentations developed so far that they touched these questions — though not fully satisfying all (parts of) the audience, as the above title indicates and next is clarified.

Upfront: Probably everybody agrees that the CAFC's workload is enormous and it alone suffices for preventing the CAFC from quickly reacting on the Supreme Court's indications of how to deal with the new known and unknown properties of ETCIs[1.b)]. These indications have meanwhile been stepwise clarified over the years[5,…,415]/1.c)/e)/f) by FSTP-Technology, published on its Internet-blog, but ignored by the US patent community. The latter hence couldn't recognize their huge potential — making investing time into it much more than just worthwhile.

Thus, the CAFC's lag time is partially self-inflicted by clinging to SPL-truths from pre-*MBA*-times – confirmed by this panel, most significantly: that consistency of reasoning may have merits elsewhere but not in SPL-precedents – today being misconceptions, caused by incredibly high&risky R&D investments into a Biotech-ETCI, amounting to billions of US$. The Supreme Court's framework recognized this SPL-paradigm refinement, and FSTP-Technology elaborated on it[e)/f)].

I.e.: The CAFC does not recognize this SPL/ETCI-metamorphosis. Two key indicators are that it nowhere notes that

- post-*MBA*-SPL and hence all ETCIs are of 'Finite Predicate Logic, FPL', dramatically simplifying decision making, and
- this indeed simplified new thinking is nothing else but a smooth refinement of hitherto in classical thinking not dared and not enabled preciseness, scientification, and simplification as indispensable for automatation.

History shows that in any knowledge area any such vastly simplifying paradigm shift has prevailed[f)]. I.e.: The US Highest Courts will on this basis reestablish consistency in SPL-precedents — as R&D-investors are longing for!

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[3].**a** The author explicitly emphasizes that his evaluations of the CAFC's PE decisions result from scientific work, derived by a brand new and without any training by anybody immediately precisely conceivable and automatically by the IES interpretable 'Cognition Mathematics' based 'Innovation Description Language, IDL' — for interpreting natural language sentences encoding metarational statements, here of patent(application)s for ETCIs and the resp. legal statements.

.b simply by not recognizing the need of the requirements **4.)** & **5.)** stated by *Alice's* PE-analysis in the PE-test derived from this PE-analysis

.c **Justice Breyer**[69]: "Different judges can have different interpretations. All you're getting is mine, ok? I think it's easy to say that Archimedes can't just go to a boat builder and say, apply my idea **[**i.e. the natural phenomenon of a boats' water displacement**]** …. Everybody agrees with that. But now we try to take that word "apply" and give content to it. And what I suspect, in my opinion, *Mayo* did and *Bilski* and the other cases, is to sketch an outer shell **[**i.e. framework**]** of the content, hoping that the experts, you and the other lawyers and the CAFC, could fill in a little better than we had done the content of that shell…" **[brackets added].**

.d which clearly models — especially in *Alice*'s specification, though nontrivially[415] — the dependency of its PE-analysis on these 5 requirements to be met by an ETCI for being D/PE/PA and that this ETCI's such properties are based on their fulfillment, from which immediately follows that and why the CAFC's/USPTO's 2-step PE-test is an incomplete implementation of the *Alice*'s PE-analysis = ETCI's PE-property specification[1.a)].
I.e.: The CAFC refuses to acknowledge that ETCIs are a new and economically utmost important kind of its own other than CTCIs.

.e compared to preceding paradigm shifts in major knowledge areas (which took dozens of years at least, if not centuries), this one — created by the Supreme Court's *MBA*-framework, elaborated on by a new 'Mathematical Cognition Theory'[182], and implemented as FSTP-Technology by the IES prototype, going public still this year (for friendly testers) — was performed virtually instantly. And with a comparably ridiculously low private financial investment of about 25M US$ for a semiotically so far reaching paradigm refinement that it multiply and fundamentally impacts on any future innovation (besides a considerable personal investment by the developer crews in Berlin and Bangalore).
Most of the time required has been spent for grasping this refined SPL-semiotics of SPL-pragmatics for ETCIs, mathematically assessing it is consistent and the minimal refinement of the classical SPL that meets all requirements stated by the Supreme Court's *MBA*-framework, and practically assessing it is indeed fully applicable to all by ETCIs caused problems of SPL-precedents about them — before contacting a broader public, which from now on is happening.

.f In hindsight, these 5 requirements of Section I cognitionally implied that the Supreme Court's "***MBA*-framework**" alias "**ETCI-framework**" had achieved already — especially by this framework's PE-analysis in *Alice* and unnoticed by the science communities concerned, even that of AI[2] — a really far reaching and totally surprising scientification of the basics of creating inventions & innovations. These decisive & decidable cognitions that the ETCI-framework enabled are in no way recognizable without meeting these 5 requirements. Not a single one is dispensable thereby.
In this short note only the cognition theoretical aspects of this '**SPL paradigm refinement**' for ETCIs are considered, abstracting from the many other and equally important aspects of this SPL paradigm refinement, e.g. from its enormous productivity increase in all today's patent businesses, by a factor of 10 at least[9.c]. These aspects take SPL/ETCI-precedents from its today's 'manufacture'-level of development to the 'post-industrial' one (i.e. to a very advanced and rapidly further automating 'AI'-level of development)[182].

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IV. Aftermath

Scientifically[410,415] only one correct interpretation exists of the Supreme Court's *MBA*-framework and of its requirements **1.)-5.)** (see Section I). This does not exclude that a simpler (as incomplete) interpretation of this framework, e. g. the CAFC's/USPTO's 2-step PE-test[406,415], finds some ETCI*s to be PE* **–** in spite of the finer FSTP-Test (of more subtests[406] than the former) correctly finding this ETCI* ^{n}PE[415ftn3.e].

Only at first glance would investors welcome this 'PE* generosity' of the CAFC's/USPTO's 2-step PE-test. Such a patent* – – using this much coarser post-*MBA*-framework SPL-interpretation, as usual today (i.e. not the complete and hence finer FSTP-Test) — is namely (even if it is D*$\wedge$PE*$\wedge$PA*, but not (D v PE v PA)) easily destroyable. By contrast, simply by having drafted an ETCI* according to the Supreme Court's *MBA*-framework — automatically controllable by the IES and thus excluding any legal error — would have rendered it totally robust[355,372].

This ANNEX to[415] finally notes that it clarified just one of the enormous international advantages that the Supreme Court created for the Biotech innovation economies **–** with its ETCI-framework[3.f] and its Solomonic 2-step PE-analysis in *Alice*.

The FSTP-Project's Reference List

FSTP = Facts Screening/Transforming/Presenting (Version of 15.10.2017*)

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

[2] AIT: "Advanced Information Technology" alias "Artificial Intelligence Technology" denotes cutting edge IT areas, e.g. Knowledge Representation(KR)/Description Logic (DL)/Natural Language (NL)/Semantics/Semiotics/System Design, just as MAI: "Mathematical Artificial Intelligence", the resilient fundament of AIT and "Facts Screening/ Transforming/Presenting, FSTP"-Technology, developed here..

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