No. 12-398

IN THE
Supreme Court of the United States

ASSOCIATION FOR MOLECULAR PATHOLOGY, et al.
Petitioners,
v.
MYRIAD GENETICS INC. et al.
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE SIGRAM SCHINDLER BETEILIGUNGSGESELLSCHAFT mbH, IN SUPPORT OF NEITHER PARTY

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STATEMENT OF IDENTITY AND INTEREST

Sigram Schindler Beteiligungsgesellschaft mbH and its subsidiaries (collectively "SSBG") are research-based high technology companies located in Berlin, Germany, developing and selling products and services all over the world, including the US, via TELES AG. SSBG is a majority shareholder of TELES AG, founded by Sigram Schindler, at that time full professor at the Technical University of Berlin's Computer Sciences Department [1]

SSBG's ability to invest in high-tech research is dependent upon the intellectual property protections accorded under the global patent systems, in particular in the United States and Europe. Strong patent systems require that the patents issued are consistently interpreted so that the metes and bound of the protected subject matter is clear and consistent. SSGB, therefore, has a vested interest in supporting the US patent system in its on-going development in adjusting itself to the needs of sectors of the economy based on emerging technologies. This court provided clear guidance and mandates in the *KSR/Bilski/Mayo* line of decisions to further advance US patent precedence in this area

This brief, in support of neither party, is filed on behalf of *Amicus Curiae* SSBG – which has no financial interest in either side.

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[1] Pursuant to Supreme Court Rule 37.6, amicus curiae states that no counsel for a party authored this brief in whole or in part, and no entity or person other than amicus curiae, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief. Letters from the parties consenting to the filing of this brief are on file with the Clerk.

SUMMARY OF THE ARGUMENT

This Amicus Brief aims at contributing – to the dispute of patent-eligibility of the human genome – the view on it of advanced IT/epistemology/mathematics/physics, as developed in SSBG's interdisciplinary FSTP project.

This contribution suggests deciding the question by applying a test to such an invention. This test checks whether it functionally is defined precisely or it is only an abstract idea – implying, this invention also has a fuzzy if not undecidable scope. The author has recently submitted this "not only abstract idea" test in an Amicus Brief to the CAFC which had asked for such a test for a "computer-implemented" invention.

The subsequent section starts by presenting that it is reasonable to approach the patent-eligibility problem of the human genome – given the very thoughtful but equally controversial discussion of this issue – by avoiding stating speculative facts of fundamental physics and instead trying to bring consensus into this discussion.

Such a solution of this problem would enable granting very strong and stable patents for human genome based inventions – yet only if the scope of protection granted to the invention is so clearly defined that it cannot preempt research and/or innovations outsides of the scope of protection granted. Academic research ought not to be hindered by patents at all – at least relating to the human genome.

The requirement to be clearly understood – to be met particularly by the scope of protection granted to such an invention, i.e. not by the physical realization of the human genome's functionalities – implies a serious limitation as to the "philosophy" of specifying the claimed invention, explained in detail by the next sections.

In principle, this limitation is necessary for warranting that a claimed invention, once it passed the 35 U.S.C. § 112 test in an unquestionable way, would also make the 35 U.S.C. §§ 102, 103, 101 tests easy – i.e. avoid undecidability as to any one of them. Testing a claimed invention as to these four sections in a different sequence is problematic, anyway.

Particularly striking is that – as to patent-eligibility of the human genome – the suggested test makes the existing conflict over the human genome obsolete: While it indicates the human genome to be patent-non-eligible, it also indicates commercially equivalent human genome based inventions patent-eligible. As a result, such patents even would be significantly stronger.

Finally, if a human genome based invention passes this not only abstract idea test, it – by logical implication of the definition of this test – also is non-preemptive, i.e. its scope of protection by US patent law is limited to exactly this well-defined scope. This aspect of the non abstract idea test, namely its side effect of checking the invention for non-preemption, was not stressed in our CAFC Amicus Brief, as it was not really material in the *CLS* case.

ARGUMENT

I. PATENT PRECEDENTS SHOULD AVOID FUNDAMENTAL PHYSICS

With its *KSR* and *Bilski* decisions, and in particular with its *Mayo* decision, this court clearly demanded that the US patent precedents cater also to needs of sectors of the economy based on emerging technologies. Many of them are often "(fictional) model" based – in contrast to MoT based – e.g. gene technology. But should such models comprise speculative notions of fundamental physics?

The human genome is a fictional model relating a man's traits and genes. It is inherently based on speculative fundamental physics notions – e.g. the physical forces bonding atoms together to molecules, or these molecules'/genes' physical encodings of their geno-/pheno-type relational potentials – which patent precedents hitherto abstracted away. But this abstraction recently has been abandoned, and human genome based patent precedents started to tamper with the human genome model's fundamental physics realization. Due to the latter's above described uncertainties, such patent precedents cannot be sure that e.g. some "physically isolated" gene does not exist in nature, or its "physical isolation" does create anything functionally new.

Sections II-IV show: Human genome based patent precedents need not deal with uncertainties of fundamental physics. It may stay in the world of creating/describing such inventions in the language of the person of ordinary skill in genetics.

But first **a)** and **b)** explain the two above exemplary risks inherent to using fundamental physics in human genome based genetics.

a) First of all, one day it may turn out that this isolated gene exists in nature. But even if not: Then physically there still is doubt about the being of the physical forces gluing atoms together to extremely complicated molecules such as the human DNA ones. I.e.: The meaning of the term "isolating" such a complicated gene needs clarification. Namely: Is this isolation really a man's intentional creation to be represented by an "inventive concept"[3),III.2Def1,ftn4)]? If this isolation is achieved by just using a "natural phenomenon", then it is not subject to patent-eligibility in the US, up to this court.

There is a viable argument that molecular biology here indeed uses in a known way a natural phenomenon (not really understood). The reason being that molecular biology as to such questions must blindly trust bio-chemistry, which must blindly trust physical chemistry, which must blindly trust fundamental physics, which uses mathematics for fabricating different models allegedly answering such questions as to atoms'/molecules' electromagnetic affinities to each other enabling the formation of the large and diversified human genome (actually observable by visible light wave-length microscopes) and hence as to isolating its genes. Thereby the exact reasons of such affinities and hence implications of such an isolation – assumed, in any such model, always based on

the individual atoms'/molecules' electrons for explaining the molecular binding forces between them – are and will remain unknown on the atomic level as their components as such, e.g. electrons, are not observable (see Heisenberg's "uncertainty relation"). One of the godfathers of physical chemistry, Linus Pauling, never claimed that he was considering these bonding forces as something other than a natural phenomenon, for which to analyse he used a knowingly speculative fundamental physics model, namely that of Nils Bohr, which rightfully still is used in biochemistry. In fundamental physics meanwhile Bohr's atom model is replaced by Schrödinger's model and then by quantum field theoretical models.

This implies the question, whether leveraging on such a speculative fundamental physics model underlying a "natural phenomenon" by known means developed to this end – "just applying it" for gene isolation, as this court referred to in its *Mayo* decision – is patent-eligible.

b) In view of a) the question exists, whether the physical isolation as such of a gene would not make it non-patent-eligible. This problem might be fixed only if its biological functionality were new, at least. But this argument also is barred if the claimed invention assumes (as regularly is the case) that its isolation has no impact on its functionality; otherwise clarifying b) needs some more words but arrives at the same end – due to the obscurity of the physical encoding of the human genome's biological functionality.

To summarize **a)** and **b)**: Fundamentals of physics in human genome patent precedents introduce into it their uncertainties. Hence, they prevent granting dependable patents in this field – as they expose their inventions to legitimate attacks by all kinds of physical theories.

But dependable human genome based patents are indispensable for stimulating research in such technologies – for sake of the overwhelming humanitarian benefits they undoubtedly embody – by making such research also economically interesting. After all, this was and is the primary social justification of patent law: This is an issue of all overarching importance – clearly not an all overruling one.

That, independent of the above physical fundamentals, dependable human genome based patents can be granted in a responsible manner, as demanded by this court, is explained in the next sections. They will show that this requires in particular that these patents' scopes are "well-defined". This is a mathematical term from the early 20th century when the scientific foundations of mathematics had to be cleaned up and hence had often to be stated "the definition used is already cleaned-up", i.e. from a period of time in which mathematics learned that it then partially was built on sand. This insight currently comes up in "model based" patent precedents, too – taking it to a higher level of evolution as well (as explained in[3),*]).

In total: The broadly known and vastly mental DNA model of the human genome – not aiming at clarifying how fundamental physics enables it, but backed-up by much biological and legal experience

with it – is a clear and sufficient legal basis under society's control. Expanding it to comprise fundamental physics models is legally not needed by patent precedents and, in fact, exposes it to incalculable risks.

II. THE 'NON ABSTRACT IDEA' TEST OF THE HUMAN GENOME AND OF A HUMAN GENOME BASED INVENTION

A PTO's or court's decision as to a human genome based claimed invention (i.e. not focusing just on the human genome) needs of its inventive steps only their descriptions by creative/inventive concepts, of which none needs to refer to a physical modification of a physical human gene. All such references – by independent inventive concepts embodying this invention over prior art – in the patent's specification and the respective claim's wording need to address only the model world of biological chemistry and hence are next-to-trivial. And this also holds for the "non abstract idea" test of a human genome based invention. But: This test requires the patent disclosing the invention to specify also **the practical problem it solves** as well as **its simple independent inventive concepts**[2].

This test of an invention – for it not to be an "abstract idea" – has two steps:

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[2] In patent language the terms "invention", "system", method", "solution", "problem", … stand for "type"- alias "class"-kind notions, as called in IT.

1) Disaggregating the claimed invention's inventive compound concept(s) into its(their) said simple independent inventive concepts,
2) Verifying that – if the invention is reduced by a property described by at least one of said concepts of 1) – performing this reduced invention does not solve the problem.

A patent granted for an invention with a so defined scope of protection logically cannot preempt any innovation outside of this scope.

By its so defined "no abstract idea" test of the human genome, this Amicus Brief already presented its answer to the question here at stake. Additionally it addressed why this rigor and simplicity causes no problem for economic stimulus provided by patent law in this extremely important area. The logical consequences of this rigor and simplicity namely are:

1) No, the human genome model is not patent-eligible, as this test shows that it is an abstract idea – already within the simple model world of biological chemistry (and the more if it were refined by a fundamental physics based model). Reasons are: It is impossible, for the human genome, to
   a. define the problem it has to solve – the bulk of them is unknown – and
   b. therefore define the respective simple independent concepts it, seen as a hypothetical solution, would use to this end, and
   c. therefore show that such hypothetical simple concepts are independent, and

d. therefore show that said concepts meet the step 2 requirement, as clarified below.

2) Yes, dependable patents as to all kinds of human genome based inventions may be granted, but only if their scopes are well-defined, i.e. they pass the above "non abstract idea" test, which implies that they define the problems they solve and the simple independent inventive/creative concepts they use to this end – elaborated on in Section IV.

III. COMPOUND CONCEPT DISAGGREGATION

The first step of the above test of the claimed invention at issue, its "compound inventive concept disaggregation" – induced by this court's *KSR*, *Bilski*, and in particular *Mayo* decisions[2)] – is indispensable for finding an unquestionable basis for precisely determining its scope of patent law protection.

Mathematics knows since centuries the need of an unquestionable basis for making precise statements: Here an "orthogonal coordinate system" usually serves as such a basis – often an "independent coordinates system" is sufficient. This court builds on this technique of Mathematics by its use of the term and notion "creative alias inventive concept", in its above decisions, when asking for precise descriptions of properties of claimed inventions: Its "creative/inventive concepts" of an invention determine its state space exactly as the Mathematics' "independent coordinates" of a system determine its state space (i.e. the space they both "span").

IT also builds on exactly this technique – since decades and even using the term/notion "concept" – for describing properties of new systems. There, this precisely definable notion of concept was developed, in the 1970s, for specifying data base systems, and since then elaborated on in its branches of Artificial Intelligence (AI), Natural Language (NL), Description Logic (DL), Knowledge Representation (KR), …. Today it is a fundamental notion in "advanced IT"[3].

Using this term/notion of "concept" in patent jurisdiction, i.e. in a NL environment, requires observing still another fundamental measure of caution, as discovered in the 1970s by David Parnas, one of the godfathers of SW-System-Design technique. Namely, the additional indispensable principle of "separation of concerns" in requirement statements in IT is the same as "disaggregation of compound inventive concepts" described in this Brief[3].

While compound concepts in natural languages are felt as being intuitive and hence are absolutely ubiquitous therein – e.g. in wordings of patent claims – they logically are extremely error prone (just as non-separated alias compound concerns are error prone in requirement statements in specifications of IT systems). By contrast, experience shows that independent inventive concept are next to trivial[3] – in particular if made "binary", also always trivially achievable[3] – and hence are logically error resistant. Finally, the separation of concerns requirement may exceed that of independence.

Most of the complicated discussions in patent precedents – in particular about testing a claimed invention as to the above quoted 4 §§ – are clearly due to the attempt to become precise about the relations of the meanings of these four sections to the meaning(s) of the invention's compound inventive concept(s), i.e. without first disaggregating it(them) into its(their) independent inventive concepts, also separating their concerns.

Yet it is known that in this way preciseness is often not achievable at all[2]!!! Even worse, accepting such compound inventive concepts in claim construction may result in the courts' decisions on them to be inconsistent and hence unpredictable. I.e.: These phenomena may be vastly avoided, in patent disputes, by admitting in its claim analysis solely simple (binary) independent disclosed inventive concepts – also if the claim's wording uses compound inventive concepts. There is absolutely no need to tolerate in patent precedents – even not when deciding on model based inventions such as human genome based inventions, as explained further down – dependent and/or "concerns not separating" concepts.

In its *Mayo* decision, the demands of this court clearly imply for the US patent precedents to insist in the just described state-of-the-art claims analysis that avoids such problems (clearly recognized in advanced IT).

So far this section explained the two quite different requirements, unquestioned in all advanced IT, to be met for enabling precise statements as to an invention, which imply the indispensable

decomposition of compound inventive concepts into their simple independent inventive concepts. Putting it simply, these are,: The need of a dependable "coordinate system" for the predicates describing the invention's properties, and the need of assessing these properties represent separate and hence (usually) simple concerns involved in the inventive problem solution alias invention.

Without meeting these requirements, consistent arguing about model based inventions is impossible. But meeting them does not yet show that there is no need to leave the NL (though that of a person of pertinent ordinary skill) style of communications in model based patent precedents and to divert into the artificial thinking of the resp. model, in human genomes based inventions being the language of fundamental physics.

Disaggregating compound inventive concepts is nothing new in US patent precedents – but exactly what the *Mayo* decision asked for, and is consistent with the *KSR* and *Bilski* decisions as well as the recent CAFC decisions (also doing it implicitly)[3]. Yet, it should be understood as a clearly separate first step, being very significant for the claimed invention's test under the above 4 §§ 112, 102, 103, and 101. From the point of view of advanced IT, this first step is indispensable anyway.

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[3] "An Innovation Expert System, IES, and its PTR Data Structure, PTR-DS", Sections g.1-10 of footnote 4), on www.fstp-expert-system.com,

IV. THE DNA MODEL AND GRANTING PATENT PROTECTION TO HUMAN GENOME BASED INVENTIONS

This section first clarifies in **IV.1** the overall functionality that the mental DNA model of bio-chemistry represents of genetics, i.e. its process of cell division&diversification, and how it describes this functionality by means of "DNA concepts". **IV.2** explains in general terms, why this DNA model enables describing all genome based claimed inventions as required by the *Mayo* decision.

IV.1 Describing the Bio-Chemistry's Model of Genetics by DNA Concepts

This subsection shows how part of the commonly known model of the working of genetics with its all overarching DNA based bio-chemical process of cell division&diversification, the so-called DNA model, would be described by using the advanced IT notion of "concept". This DNA process describes the generation of compound DNA concepts of a developed genome out of elementary DNA concepts of its initial/undeveloped genome(s).

This description of the DNA model may focus, here, on its basic principles. This suffices already for precisely describing the kind and height of the creativity/ inventivity embodied by a human genome based invention over prior art, as needed for deciding whether this invention would pass its test under 35 U.S.C. §§ 112, 102, 103, and 101. The so focused description of the DNA model remains in this context (as set by the Sections I-III), comprising that it is plainly mental (i.e. totally abstracts from

its vastly unknown physical fundaments) and may ignore also all other aspects of itself and of the invention, which are not related to these tests of it. Its description then is reducible to this context, too, i.e. to the following.

The DNA model's principle of a genome's cell division&diversification is the mirror image to the principle of an invention's compound inventive concepts disaggregation. In other words: The mental process of disaggregating all compound concepts of a genome developed by at least one step (i.e. the disaggregation of all of this genome's traits at this stage) into all their elementary concepts of this initial genome (i.e. of its genes) – called "fully decoding" this genome at this stage – is the inverse of the mental process of the bio-chemical DNA model, which describes this initial genome's cell division&diversification into this developed genome.

Here this mental bio-chemical process may be further reduced to its start/ stop relation between the (set of all by this process affected) genes of this initial genome to (the set of all affected) traits of this developed genome. Applying this reduction to the complete mental bio-chemical process of two just fertilized human genomes to a fully developed human being, it may be represented also as a relation between the set of all their genes and the set of all traits of this human being.

This abstract principle of the DNA model is clarified in some more notional detail, next, in other colloquial terms. The mathematical principle of its relation – in technical detail vastly unknown for the human genome – is known[3)III.2.,Def3].

Anyone specific alias "individual" human genome and its genes exist in a resp. specific form alias instantiation. Genetics denotes any such form of a gene as an "allele" and of a genome's property "trait". IT terminology would denote genes, codons, genomes, phenotypes and their properties as "types" alias "classes", and their individual instantiations as "objects". Allele, trait, feature are object names, but genetics often calls objects just as types. Physical generations/interactions of objects are outside of the scope of this brief (and vastly unknown[I]).

In the description by means of concepts a particular use of the DNA model – e.g. for modelling particularities of a genome or therein of a process – the term "element" may denote any use specific said class or object, and any such "DNA concept" represents this element's property resp. a feature of it in this use. Hence, an element's DNA concept definition is simply given by the set of features of its property in this use of the DNA model – be the element therein e.g. a phenotype or a gene or an object of one of them, i.e. a trait resp. allele. This feature set of a DNA element may comprise its known as well as its novel features, i.e. of e.g. an allele its natural and its – by an invention – modified division/diversification capability.

These DNA model terms/notions enable specifying, by its use, any human genome based invention: Any such specification comprises a few traits (being compound DNA model concepts), a number of alleles (elementary DNA model concepts), and inventive nonDNA model concepts, together defining the invention.

IV.2 Describing a Human Genome Based Invention by Concepts

If a human genome based invention is created, which seeks protection by patent law, its inventive concepts got to be disclosed by its specification – up to the *Mayo* decision.

The above description of the DNA model shows that none of the DNA concepts is inventive in the sense of US patent precedents – any such concept describes a property (feature) of an element (object) that the DNA model assumes to exist in the nature, though it need not yet be known by bio-chemistry. .

Thus, such a human genome based invention got to be described by its inventive nonDNA concepts independent[2)III.2.,Def2] of those of the DNA model, i.e. inventive properties (features) of this invention's non DNA element(s). Such inventive nonDNA concepts may describe, for this invention, e.g. the way in its genome (object) a gene or allele or codon or property or trait or … is identified, or the minimal number of steps on this way, or these steps costs, or a side-effect of it/them on another element of the DNA model, or an impact on it/them by another such inventive nonDNA concept, or …, but no fundamental physics statement. The mental DNA model sets no other limit as to defining such inventive nonDNA concepts' interactions with and/or impacts on DNA concepts – but it assumes that such interactions and/or impacts are, as usual, verified by bio-chemical experiments.

Thus a *Mayo* decision conforming description of a human genome based claimed invention then got to identify:

- At least one trait, being a modified compound concept definition of DNA phenotype object, thus reflecting the impact of an inventive/nonDNA concept on it, and at least one of the two following items:
- At least one allele, being a potentially modified concept definition of its DNA genotype object, thus potentially reflecting the impact of an inventive/nonDNA concept on it, and/or
- At least one relational object, being a potentially modified relational object of the above relation between features of said two concept definition sets, thus potentially reflecting the impact of an inventive/nonDNA concept on it.

That a notionally so structured description of a human genome based claimed invention actually solves the problem set out by the specification to be solved by it got to be confirmed by the person of pertinent ordinary skill based on experiments, as usual.

Finally note that performing this non abstract idea test has required the prior testing of said inventive concepts under § 112 as to their individual proper disclosures, under § 102 as to their novelty over a prior art, and under § 103 as to their non-obviousness over a combination of prior art teachings (more precisely: as to their not being anticipated by a combination of prior art teachings[2),III.1]). Those of these inventive concepts, which are "not drawn into a natural phenomenon" implied by their definitions by means of fundamental physics, are

those for which the *Mayo* decision asked – as they provide the basis for indicating said claimed invention's patentability. To this end, these inventive concepts must also be tested for their independency. Dependent inventive concepts namely might disguise the factual obviousness of their claimed invention over prior art (what actually happened in patents granted for model based inventions, as explained in detail elsewhere[2),III.2]).

CONCLUSION

A patent-eligibility test of a human genome based invention should start with assessing its scope is well-defined by applying the suggested non abstract idea test to it. The therein involved disaggregation of the invention's compound inventive concept(s) into independent inventive concepts should not refer to fundamental physics but only to the notions of the plainly mental DNA model.

Putting it more generally: For regaining clarity, predictability, and stability as to legal decisions on model based inventions and patents (to be) granted – not only but also as to human genes based ones – the sole unquestionable option seems to be to grant patent protection only to inventions of clearly defined scopes, as verified by their above "not abstract idea" test and refraining from using fundamental physics statements therein[4)].

Proceeding this way is consistent with 35 U.S.C.. Among the economically leading regions of the world, proceeding this way today is only possible under the US jurisdiction with its Supreme Court, its CAFC, and their substantial responsibilities under the US Constitution. It would take the US patent precedents to a level of development, which has been enabled by advanced IT, and which is capable of dealing with the model based inventions of the societally important branches of economy based on advanced sciences and technologies.

[4)] www.fstp-expert-system.com highly appreciates comments

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