United States Court of Appeals for the Federal Circuit

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff-Appellant,

v.

BIOGEN IDEC,
Defendant-Appellee,

and

GLAXOSMITHKLINE,
Defendant-Appellee,

and

MERCK & CO., INC.,
Defendant-Cross-Appellant,

and

CHIRON CORPORATION, KAISER-PERMANENTE, INC., KAISER PERMANENTE VENTURES, KAISER PERMANENTE INTERNATIONAL, KAISER PERMANENTE INSURANCE COMPANY, THE PERMANENTE FEDERATION, LLC, THE PERMANENTE COMPANY, LLC, THE PERMANENTE FOUNDATION, THE PERMANENTE MEDICAL GROUP, INC., KAISER FOUNDATION HOSPITALS, KAISER FOUNDATION ADDED CHOICE HEALTH PLAN, INC., AND KAISER FOUNDATION HEALTH PLAN INC.,
Defendants.

2006-1634,-1649

Appeal from the United States District Court for the District of Maryland in Case No. 04-CV-2607, Judge William D. Quarles, Jr.

Decided: August 31, 2011

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Before RADER, *Chief Judge*, NEWMAN, AND MOORE, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* NEWMAN. Additional views filed by *Chief Judge* RADER, in which *Circuit Judge* NEWMAN joins. Dissenting opinion filed by *Circuit Judge* MOORE.

NEWMAN, *Circuit Judge*.

This appeal reaches us on remand from the Supreme Court,[1] the Court having vacated our decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 F. App'x 866 (Fed. Cir. 2008), in view of the Court's decision in *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218 (2010). We have received additional briefing, and now reconsider the appeal of the district court's rulings, on motions for summary judgment, in *Classen Immunotherapies, Inc. v. Biogen IDEC*, No. WDQ-04-2607, 2006 WL 6161856 (D. Md. Aug. 16, 2006); 381 F. Supp. 2d 452 (D. Md. 2005).

The Court's remand concerns the question of patent-eligibility, 35 U.S.C. §101, of the subject matter claimed in the Classen patents in suit. The question arises on the district court's application of the common-law exclusions from §101 of "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). The district court granted summary judgment that all of the claims in the Classen patents are ineligible

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[1] *Classen Immunotherapies, Inc. v. Biogen IDEC*, 561 U.S. ___, 130 S. Ct. 3541 (2010) (GVR). GVR is a procedure whereby the Court, having decided an issue in another case, Grants, Vacates, and Remands "for the sake of judicial economy—so that the lower court can more fully consider the issue with the wisdom of the intervening development." *United States v. Norman*, 427 F.3d 537, 538 n.1 (8th Cir. 2005) (citing *Lawrence v. Chater*, 516 U.S. 163, 167–68, 174 (1996)).

for patenting because they are directed to the "abstract idea" that there is a relation between the infant immunization schedule for infectious diseases and the later occurrence of chronic immune-mediated (non-infectious) disorders. We review the question of eligibility with the Court's guidance in *Bilski v. Kappos* that "[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts," exclusions from patent-eligibility should be considered in view of the particular case and applied narrowly. 130 S. Ct. at 3229.

We conclude that the claimed subject matter of two of the three Classen patents is eligible under §101 to be considered for patenting, although we recognize that the claims may not meet the substantive criteria of patentability as set forth in §102, §103, and §112 of Title 35. However, questions of patent validity are not before us on this appeal, for the only motion for summary judgment under these substantive provisions was based on prior use asserted by defendant Merck, and was denied by the district court because facts were in dispute. Denials of summary judgment are not appealable.

The district court granted summary judgment that the claims are not infringed, based on Classen's failure to allege facts sufficient to establish infringement by Merck, and based on the safe-harbor provision of 35 U.S.C. §271(e)(1) as to other defendants. We affirm the judgment as to Merck. However, since §271(e)(1) is not applicable to the cited activities, we vacate the judgment that was granted on this ground.

We now consider the issues on appeal and cross-appeal.

I

SUBJECT MATTER ELIGIBILITY – 35 U.S.C. §101

In suit are three related patents, each entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or their Sequelae": United States Patents No. 6,638,739 ("the '739 patent"), No. 6,420,139 ("the '139 patent"), and No. 5,723,283 ("the '283 patent"). The inventor is Dr. John Barthelow Classen, and the patents are assigned to Classen Immunotherapies, Inc. ("Classen"). The patents state Dr. Classen's thesis that the schedule of infant immunization for infectious diseases can affect the later occurrence of chronic immune-mediated disorders such as diabetes, asthma, hay fever, cancer, multiple sclerosis, and schizophrenia, and that immunization should be conducted on the schedule that presents the lowest risk with respect to such disorders. The three patents state that Dr. Classen has discovered that

> when one or more immunogens . . . is first administered at an early age (typically prior to 42 days of age), it can substantially decrease the incidence, frequency, prevalence or severity of, or prevent, at least one chronic immune mediated disorder, and/or a surrogate marker thereof.

'283 patent col.7 ll.35-41; '739 patent col.7 ll.39-45; '139 patent col. 7 ll.35-41.

The three patents contain a total of 230 claims. The summary judgment proceedings were directed to the "representative claims" selected by Classen. The claims of the '139 and '739 patents state the method whereby information on immunization schedules and the occurrence of chronic disease is "screened" and "compared," the lower risk schedule is "identified," and the vaccine is "administered" on that schedule. Classen states that "The

patented method of the '139 and '739 patents is exemplified by Claim 1 of the '739 patent." Classen Br. 11. Claim 1 states:

> 1. A method of immunizing a mammalian subject which comprises:
>
> (I) screening a plurality of immunization schedules, by
>
> (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and
>
> (b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

> (II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

Classen states that the '139 and '739 patents are infringed when a health care provider reads the relevant literature and selects and uses an immunization schedule that is of lower risk for development of a chronic immune-mediated disorder:

> [T]he '139 and '739 patents in suit are directly infringed when a physician, hospital or other health care provider reads the relevant literature and selects an immunization schedule and immunizes a patient in accordance with the schedule which appears to have minimal risk.

Classen Br. 22. Classen states that the patents are infringed by the act of reviewing the published information, whether or not any change in the immunization schedule is made upon such review. Classen Br. 41 ("maintenance of the current schedule is step (II) of the Classen method").

The '283 patent claims the first step of the above method, by reviewing and comparing published information on the effects of immunization schedules in treated and control groups of mammals, with respect to the occurrence of immune-mediated disorders. Claim 1 was designated as representative of the '283 patent:

> 1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

Classen states that the '283 patent is infringed when a person reviews relevant information, whether the person is a producer of vaccines, a health care provider, or a concerned parent. Classen Br. 41 ("the infringer need only assess risk, it is not necessary for the infringer to conduct its own clinical trials or prove the cause of any adverse effects"). The '283 patent claims do not include performing immunizations in accordance with the information learned by the claimed method.

The three patents list over four hundred references related to immunization schedules, the occurrence of immune-mediated disorders, and various studies and reports in this field. For example, the patents cite a publication entitled "The Swedish Childhood Diabetes Study: Vaccinations and Infections as Risk Determinants for Diabetes in Childhood," L. Blom et al., *Diabetologia*, 34(3):176-81 (1991); this publication states that: "The possible association between viral diseases and diabetes has also prompted an interest in vaccinations as possible risk factors for diabetes," *id.* at 176, and describes "a nationwide incident case referent study [where] we have evaluated vaccinations, early and recent infections and

the use of medicines as possible risk determinants for Type 1 (insulin-dependent) diabetes mellitus in childhood." *Id.* The study concludes:

> When vaccinations were considered as possible risk factors for diabetes, a significant decrease in relative risk estimated as odds ratio (OR) was noted for measles vaccination . . . . In conclusion, a protective effect of measles vaccination for Type 1 diabetes in childhood is indicated as well as a possible causal relationship between the onset of the disease and the total load of recent infections.

Id. The Classen patents acknowledge that this study "suggested that vaccination against measles may influence a reduction in the incidence of diabetes," but criticize the study for the asserted absence of controls.

The Classen patents list several publications of Huang *et al.*, including "The Effect of Pertussis Vaccine on the Insulin-Dependent Diabetes Induced by Streptozotocin in Mice," *Pediatric Research*, vol. 18, No. 2, pp. 221-226 (1984). This reference was cited by the patent examiner under §102 (anticipation) during prosecution of Classen's parent application, but the rejection was withdrawn on Classen's argument that the claims require vaccination before 42 days from birth, as distinguished from the schedule used by Huang. Classen wrote to the examiner:

> Claims 2, 3, 6, 7, 9-14, 16 and 33 are rejected as anticipated by Huang et al. (1984), which alleged[ly] discloses both immunization against pertussis by administering a pertussis immunogen at 45, 55, 59 and 85 days of life (see p. 221), *and* reduction in the incidence of diabetes.

> Huang et al. (1984) cannot anticipate claims 2, 3, 6, 7, 9-14 and 16 because his first administration was to mice which were 45 days old, and claim 3 (the independent claim) requires a first administration before 42 days from birth.

Appl. Ser. No. 08/104,529, Attorney Letter, Nov. 21, 1996, at 21-22.

The district court was not asked, in the summary judgment phase, to consider the effects of these and other references on the substantive conditions of patentability. The Classen patents state that "prior to the present invention, chronic immune mediated diseases, such as diabetes mellitus, were not considered vaccine complications." '283 patent col.3 ll.54-56; '139 patent col.3 ll.54-56; '739 patent col.3 ll.54-56. However, issues of validity based on prior publications were not presented for summary judgment. The only patentability issue was raised in Merck's motion for anticipation based on prior use, as we discuss in Part II, *post*.

The defendants' motions for summary judgment included the ground that the subject matter did not meet the threshold eligibility requirements of 35 U.S.C. §101. In granting this motion, the district court accepted Classen's theory that there is a relation between childhood immunization schedules and the occurrence of chronic immune-mediated disorders. The defendants challenged the correctness of Dr. Classen's theory, citing a study by Dr. Frank DeStefano for the Centers for Disease Control, published as "Childhood Vaccinations, Vaccination Timing and Risk of Type I Diabetes Mellitus," *Pediatrics*, Dec. 2001. The district court did not hold a *Daubert* hearing – about which Classen now complains – but accepted Classen's premise for the purpose of deciding eligibility of the subject matter under §101.

The district court stated that the claims "describe little more than an inquiry of the extent of the proposed correlation between vaccines and chronic disorders." *Classen*, 2006 WL 6161856, at *5. The court observed that "thinking about" the risks of vaccination is a mental process, and held that the claims are for an abstract idea and therefore not eligible for patenting. On the initial appeal of that ruling, this court applied its en banc decision of *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), held that the Classen methods are not associated with a machine and do not transform matter, and affirmed the district court's holding of ineligibility under §101 on that ground. Now upon the Supreme Court's ruling in *Bilski v. Kappos* that the machine-or-transformation test is not the sole standard of eligibility for patenting, we again review the district court's decision, with the benefit of this court's analyses of eligibility in *Research Corporation Technologies, Inc. v. Microsoft Corporation*, 627 F.3d 859 (Fed. Cir. 2010); *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted*, _ S. Ct. _ , 2011 WL 973139 (June 20, 2011); and *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, _ F.3d _, 2011 WL 3211513 (Fed. Cir. July 29, 2011).

The defendants argue that the Classen methods are directed to no more than the steps of reading published information, that the "determining" and "comparing" steps of the claims are performed in the mind, and that any immunizing step is simply conventional activity, citing the Court's negation of the "notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process," *Parker v. Flook*, 437 U.S. 584, 590 (1978).

Classen disputes this characterization, and argues that Dr. Classen discovered a method of immunizing that lowers the risk of chronic immune-mediated disease. Classen states that this method is not an abstract idea, but a new and useful application of a newly discovered scientific fact. Thus Classen argues that the method is within the statutory classes of patent-eligible subject matter. Classen also points to the subordinate claims that were not considered by the district court, that are directed to specific immunogens, specific immunization schedules, and specific immune-mediated disorders. Classen states that even if the representative claims are deemed to be unduly broad, other claims are more specific and cannot be characterized as "abstract." Classen states that these other claims were not considered by the district court, and were improperly invalidated on summary judgment.

A. The §101 Threshold

The statement of patent-eligible subject matter has been substantially unchanged since the first Patent Act in 1790. As now codified:

> §101. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Interpretation of this provision early reached the courts in the context of charges of infringement, where the parties disputed the scope available to the patent. In 1839 Justice Story referred to patents as "securing to the whole community great advantages from the free communication of secrets, and processes, and machinery, which may be most important to all the great interests of society, to

agriculture, to commerce and to manufactures, as well as to the cause of science and art," *Blanchard v. Sprague*, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1518) (Story, J.), and also explained that "a claim for an art or principle in the abstract, and not for any particular method or machinery," is "utterly unmaintainable in point of law," *Wyeth v. Stone*, 30 F. Cas. 723, 727 (C.C.D. Mass. 1840) (No. 18,107) (Story, J.). In *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852), the Court reiterated that "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."

These principles, based on the statute and elaborated in the common law of patents, continue to be reinforced. In *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), the Court considered the new concepts and capabilities of the biological sciences, and stated:

> The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.

Id. at 315. Concurrently, the Court was considering the evolving fields of computer science and technology, and observed that while the exclusion from patentability of abstract principle and fundamental truth is well established in the common law, the boundary between abstract principle and practical application may vary with the subject matter. Thus in *Diamond v. Diehr*, 450 U.S. 175 (1981), the Court stated that "[i]t is now commonplace that an *application* of a law of nature or mathematical

formula to a known structure or process may well be deserving of patent protection," *id.* at 187. The Court explained in *Diehr* that "Arrhenius' equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold by §101." *Id.* at 188.

These principles have steadfastly guided the patent law, and in *Bilski v. Kappos* the Court reiterated its concern for "barr[ing] at the threshold," *id.,* and encouraged preservation of the legal and practical distinctions between the threshold inquiry of patent-eligibility, and the substantive conditions of patentability. The Court explained:

> The §101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy "the conditions and requirements of this title." §101. Those requirements include that the invention be novel, see §102, nonobvious, see §103, and fully and particularly described, see §112.

130 S. Ct. at 3225.

The Court in *Diehr* also discussed the statutory meaning of "new" in §101 as compared with "new" in §102; the former being a general statement governing the threshold of entry into the patent system for further consideration, the latter setting the conditions and limitations of patentable novelty:

> It has been urged that novelty is an appropriate consideration under §101. . . . Section 101, however, is a general statement of the type of subject

> matter that is eligible for patent protection "subject to the conditions and requirements of this title." Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty. The question therefore of whether a particular invention is novel is "wholly apart from whether the invention falls into a category of statutory subject matter."

450 U.S. at 189-190 (quoting *In re Bergy*, 596 F.2d 952, 961 (CCPA 1979)). The Court recognized the separation of the §101 "categories" of eligible subject matter from the §102 "conditions" of patentability, explaining that "rejection on either of [§102 or 103] does not affect the determination that respondents' claims recited subject matter which was eligible for patent protection under §101," *id.* at 191. We apply this distinction to the Classen patents, and conclude, as we shall discuss, that the '139 and '739 claims cross this threshold, while the '283 claims do not state a patent-eligible process.

B. Mental Steps

The district court held that none of the Classen claims meets the threshold under §101 of eligibility for patenting, reasoning that the method claimed in all three patents includes the mental step of reviewing the relevant literature to determine the lower-risk immunization schedule. The district court did not discuss whether the claims were anticipated or obvious in view of the prior art, and it appears that this aspect was not raised, in the district court, in the context of §101. However, precedent has recognized that the presence of a mental step is not of itself fatal to §101 eligibility, and that the "infinite variety" of mental and physical activity negates application of a rigid rule of ineligibility. *See Application of Prater*, 415 F.2d 1393, 1402 n.22 (CCPA 1969).

In *Prater* the court explained the inappropriateness of attempting to establish a universal rule for all situations that include mental activity:

> Between the purely mental and purely physical end of the spectrum there lies an infinite variety of steps that may be either machine-implemented or performed in, or with the aid of, the human mind (e.g., "comparing" and "determining"). In ascertaining whether a particular step is "mental" or "physical," each case must be decided on its own facts, considering all of the surrounding circumstances, to determine which end of the spectrum that step is nearer. It may well be that the step of "comparing" may be "mental" in one process, yet "physical" in another.

Id. Classen states that its claims include physical steps of immunization, and are not entire "[s]ets of steps occurring only in the mind," *In re Sarkar*, 588 F.2d 1330, 1333 (CCPA 1979). Classen argues that the immunization step is conducted after selection of a lower risk schedule, as in the '139 and '739 claims, or that immunization produces information about immunization effects, as in the '283 claims. Thus Classen states that its claims are not directed to an abstract idea like the commodity hedging method in *Bilski v. Kappos*.

The Court in *Bilski v. Kappos* did not define "abstract," and Justice Stevens observed in concurrence that "[t]he Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea," 130 S. Ct. at 3236. Acknowledging the difficulty of providing such an all-purpose definition, this court in *Research Corporation* stated that

> this court also will not presume to define "abstract" beyond the recognition that this disqualify-

> ing characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.

627 F.3d at 868. In *Research Corporation* the question on appeal was whether the computer-conducted method of comparing images was an abstract idea, and thus not patent-eligible under §101. This court concluded that the specified method is "functional and palpable," and that the claims recite tangible limitations on performing the specified method of comparing images.

The court in *Research Corporation*, explaining that the claims must be considered as a whole when determining eligibility to seek patentability, described the statutory role of §101 as a "coarse eligibility filter," not the final arbiter of patentability. The court explained that the substantive conditions of Title 35 must be applied, and remarked that "section 112 [is a] powerful tool[] to weed out claims that may present a vague or indefinite disclosure of the invention," and observed that "a patent that presents a process sufficient to pass the coarse eligibility filter may nonetheless be invalid as indefinite." 627 F.3d at 869; *see generally Star Scientific, Inc., v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1371 (Fed. Cir. 2008) ("[I]f reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness.").

The *Research Corporation* court also explained that the "subject matter might also be so conceptual that the written description does not enable a person of ordinary skill in the art to replicate the process," and that this too

is a matter of patentability under §112, not eligibility under §101. 627 F.3d at 869. In *Diamond v. Diehr* the Court had recognized that although subject matter may be of an eligible statutory class in §101, "it may later be determined that the respondents' process is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under §102 or nonobviousness under §103." 450 U.S. at 191. Applying this guidance, in *Research Corporation* the court held that the preferable procedure, when the claims are within the general classes of §101 subject matter and not manifestly abstract, is to apply the substantive conditions and requirements of patentability. 627 F.3d at 868-69.

The court in *Research Corporation* observed that the commercial application of the technology is relevant to deciding whether an invention is so abstract as to negate §101 subject matter. *Id.* at 869 ("Indeed, this court notes that inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act."); *see Diehr*, 450 U.S. at 184 ("Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.").

The claims of the '139 and '739 patents are directed to a method of lowering the risk of chronic immune-mediated disorder, including the physical step of immunization on the determined schedule. These claims are directed to a specific, tangible application, as in *Research Corporation,* and in accordance with the guidance of *Bilski v. Kappos* that "[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts," exclusions from patent-eligibility should be applied "narrowly," 130 S. Ct. at 3229, we conclude that the subject matter of these two patents traverses the

coarse eligibility filter of §101. Although, as we have remarked, the claims of these patents appear to raise cogent questions of substantive patentability, patentability of subject matter that is facially within the classes set forth in §101 is most reliably resolved in accordance with the conditions of §§102, 103, and 112. *See Diehr*, 450 U.S. at 190; *Research Corporation*, 627 F.3d at 868 (determining whether the claims are so manifestly abstract "as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act").

Claim 1 of the '283 patent states the method of "determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder" by reviewing information on whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder. This stands in contrast to the '139 and '739 patent claims, which include the subsequent step of immunization on an optimum schedule. Claim 1 of the '283 patent claims the idea of comparing known immunization results that are, according to the patent, found in the scientific literature, but does not require using this information for immunization purposes. Classen states, for example, that Merck induces direct infringement by parents when Merck provides and physicians distribute the book "What Every Parent Should Know About Vaccines," because the book advises parents to understand vaccines and vaccination schedules. Classen Br. 18.

Claim 1 of the '283 patent states the idea of collecting and comparing known information. As discussed in *Association for Molecular Pathology*, *supra*, methods that simply collect and compare data, without applying the data in a step of the overall method, may fail to traverse

the §101 filter. 2011 WL 3211513, at *21 (citing *Bilski*, 130 S. Ct. at 3230). The '139 and '739 claims are not simply the '283 patent steps in reverse, as the dissent argues. The "immunizing" in the '283 patent refers to the gathering of published data, while the immunizing of the '139 and '739 patent claims is the physical implementation of the mental step claimed in the '283 patent.

The distinction between a concrete, physical step of a process claim, as compared with data gathering or insignificant extra-solution activity, warrants specific consideration in the context of evolving technologies, for "Congress took [a] permissive approach to patent eligibility to ensure that 'ingenuity should receive a liberal encouragement.'" *Bilski*, 130 S. Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 308, in turn quoting Thomas Jefferson). The *Bilski* Court emphasized the "expansive terms" of §101 as evidence of the intent "that the patent laws would be given wide scope," *id.* (quoting *Chakrabarty*, 447 U.S. at 308). Thus the Court rejected the Federal Circuit's proposal in *Bilski* that the "machine-or-transformation" test should be the exclusive test for patent-eligible processes, and emphasized the classical "three specific exceptions to §101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Id.* (quoting *Chakrabarty*, 447 U.S. at 309). The Court reaffirmed the proposition that "the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of [a] formula to a particular technological environment' or adding 'insignificant postsolution activity.'" *Id.* at 3230 (quoting *Diehr*, 450 U.S. at 191-92).

The representative claim of the '283 patent is directed to the single step of reviewing the effects of known immunization schedules, as shown in the relevant literature. Although recourse to existing knowledge is the first step

of the scientific method, the method claimed in the '283 patent simply invites the reader to determine the content of that knowledge. The '283 claims do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases. In contrast, the claims of the '139 and '739 patents require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application. Determination of whether a proffered invention, as claimed, transcends an "abstract idea" is not subject to "categorical rules that might have wide-ranging and unforeseen impacts," *Bilski*, 130 S. Ct. at 3229. The invention as a whole, including the scope asserted by the patentee must be considered. We conclude that the immunization step moves the '139 and '739 claims through the coarse filter of §101, while the abstraction of the '283 claim is unrelieved by any movement from principle to application.[2]

Classen also argues that the claims of all three patents meet the machine-or-transformation test of this court's vacated *In re Bilski* opinion, citing *Prometheus Laboratories, supra*, where this court held that "claims to

[2] The dissent argues that there is "no distinction" between the claims of the '283 patent and the claims of the '139 and '739 patents. The patents, which were separately filed after the patent examiner required restriction because "the inventions are distinct," distinguish the '283 method where, according to Classen, a person simply reviews known knowledge on immunization effects, from the '139/'739 methods that require physical immunization based on that review. Even if the question as to the '139 and '739 patents were deemed to be close, the '139/'739 method of immunizing on the low-risk schedule determined by the '283 method of reading the literature, may be generously viewed as traversing the boundary into eligibility for substantive review.

methods of treatment . . . are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." 628 F.3d at 1356. On the materially different facts in *Prometheus* and in the Classen specifications, the analogy is inapt, for the claims in *Prometheus* are for a method of controlling individualized dosages of a specific drug by measuring its metabolic products in the blood of individual patients, while the Classen patents operate on published information to determine general immunization schedules. The principles applied in *Prometheus* support the patent eligibility of the Classen claims that include such transformative steps, but are not relevant to claims that require no more than referring to known information but do not include immunization in light of that information.

Viewing the representative claims of the Classen patents in accordance with their purported scope, we conclude that the claims of the '139 and '739 patents reasonably meet the threshold of §101 eligibility, and that analysis of the subject matter of these claims, and other claims in these patents, should proceed by way of the statutory criteria of patentability.[3] Pragmatic thorough-

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[3] The dissent, in its description of the claimed subject matter, states, for example, that "The Classen claims are not directed to any specific treatment steps or drugs or even any specific chronic immune disorder," Diss. Op. at 3. That is incorrect. Observe, for example, the claimed immunization schedule of administration of hepatitis B immunogen in two doses, first before 42 days after birth and second between 41-180 days after birth; identifying specific immunogens, with diabetes as the chronic immune-mediated disorder:

> '139 patent cl. 32. The method of claim 30 [including diabetes as the chronic disorder] where the hepatitis B immunogen is a

ness is thereby achieved, for extensive precedent guides the continuum from abstractness to specificity, in the context of a vast breadth of subject matter. Aided by this experience, courts may more readily resolve close questions such as are here presented. Since the patentability issues of anticipation by prior art, obviousness, and specificity were not decided by the district court, they are not before us on this appeal of the grant of summary judgment on other issues.

> killed immunogen administered prior to 42 days after birth, and at least one further immunogen is administered after 41 and before 180 days after birth in a screened schedule, and said further immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, Hemophilus influenza, tetanus, hepatitis B, polio, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme, cytomegalovirus (CMV), respiratory syncytial virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, cocidiomycosis, schistosomiasis, and malaria immunogens.

All three Classen patents contain claims whose breadth is not of "staggering" character. Our holding is not that any claim is "patentable," whatever its breadth, but that the claims are *eligible* at the threshold for review for substantive patentability.

II

ANTICIPATION BY PRIOR USE – 35 U.S.C. §102

The district court declined to decide Merck's motion for summary judgment based on Merck's asserted prior use. Merck's motion was premised on the ground that an activity for which Classen charges Merck with infringement is the same activity that was known and used and recommended by Merck more than a year before Classen's earliest filing date. Merck states that Classen's claims are anticipated by the prior use of that schedule, for "that which infringes if later anticipates if earlier," *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1573 (Fed. Cir. 1986) (quoting *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889)). The district court denied summary judgment, stating that facts were in dispute.

On appeal, Merck asks this court to decide this anticipation question ab initio, despite the general rule that the denial of a summary judgment motion is not appealable. *Kendall v. City of Chesapeake, Va.*, 174 F.3d 437, 443-44 (4th Cir. 1999). However, there is no record, no factual findings or representations on which such findings might be made, indeed no basis for factual inferences, even on the premises of summary adjudication. Thus this question is not before us on this appeal.

III

INFRINGEMENT

A. Merck's Motion for Summary Judgment

The district court granted Merck's motion for summary judgment of non-infringement, on the ground that "[t]he only specific act of infringement alleged in Classen's amended complaint was Merck's participation in or facilitation of the 2001 study conducted by Dr. Frank DeSte-

fano" for the Centers for Disease Control, and that "Merck offered uncontroverted evidence that it had no involvement in the DeStefano study." *Classen*, 2006 WL 6161856, at *2.

Classen appeals, arguing that even if Merck did not "participate in or facilitate" the DeStefano study, Merck infringed the Classen patents when Merck "reviewed" the study and "evaluated the correlation" therein. Classen states that Merck's "screening of the trials, papers, etc." of the DeStefano study of itself was an act of infringement. Classen Br. 40. Classen also argues that Merck infringed the representative claims based on its funding of studies of the relationship between the hepatitis B vaccine and the occurrence of multiple sclerosis. Classen also complains that the district court did not address Classen's allegations of Merck's contributory infringement.

The district court observed that it was undisputed that Merck did not participate in the DeStefano study, and that Classen had not "offered any evidence linking Merck to any other study or evaluation of the correlation between vaccination schedules and inciden[ce] of immune mediated disorders." *Classen Immunotherapies, Inc. v. Biogen IDEC*, No. WDQ-04-2607, slip op. at 5 (D. Md. Dec. 14, 2005). The district court stated that "Classen's claims rely on Merck's participation in or inducement of an examination of the correlation between vaccine schedules and immune mediated disorders," and that no evidence supported this charge. *Id.* We do not disturb the grant of summary judgment on the ground that no evidence of Merck's involvement in this study was presented by Classen. The district court did not abuse its discretion in declining to consider Classen's subsequent proffer of evidence, after summary judgment was granted.

The district court also acted within its discretion in declining to accept GlaxoSmithKline and Biogen's untimely motion for summary judgment on the same grounds.

B. The "Safe-harbor" Provision, 35 U.S.C. §271(e)(1)

Classen charged Biogen and GlaxoSmithKline with direct infringement on the ground that both companies participated in studies "to evaluate suggested associations between childhood vaccinations, particularly against hepatitis B and Haemophilus influenza . . . and risk of developing type 1 diabetes; and to determine whether timing of vaccination influences risk." *Classen,* 381 F. Supp. 2d at 455 (quoting Am. Compl. ¶7). Classen also stated that Biogen induced infringement by licensing technology to GlaxoSmithKline and "providing instructions and/or recommendations on a proper immunization schedule for vaccines." Am. Compl. counts I, II, and IV. The district court granted summary judgment that these activities are within the safe-harbor provision of the Hatch-Waxman Act:

> §271(e)(1). It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Classen argues that the district court erred in its application of §271(e)(1). Classen states that this statute, as enacted and intended, and as judicially interpreted, is limited to activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration. GlaxoSmithKline and Biogen respond that their reporting of vaccine relationships, or

recommendations in view of the relevant literature, or other activity in conformity with FDA regulations, are within the infringement safe-harbor of §271(e)(1). Classen states that the district court extended §271(e)(1) beyond its statutory and legislative purpose, for there is no issue in this case of submissions for regulatory approval of generic products, or like policy considerations. Classen is correct, for §271(e)(1) provides an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products. The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.

Section 271(e)(1) arose in the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 98 Stat. 1585. The House Report explains that the Act "provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent." H.R. Rep. No. 98-857, pt. 1, at 15 (1984). The Report is replete with statements that the legislation concerns premarketing approval of generic drugs. The Report emphasizes that "The information which can be developed under this provision is the type which is required to obtain approval of the drug." *Id.* at 45.

This purpose was emphasized throughout the legislative process: "The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." *Id.* Again in Part 2 of H.R. Rep. No. 98-857, at 8 (1984), the Report is explicit that "the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers

can establish the bioequivalency of a generic substitute." The Report states that "the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval." *Id.* at 30. The activities of which Biogen and GlaxoSmith-Kline are accused by Classen cannot be stretched into this role.

Every decision examining the statute has appreciated that §271(e)(1) is directed to premarketing approval of generic counterparts before patent expiration. The Court applied this limitation to medical devices in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990), stating that "[Section §271(e)(1)] allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." The Court stated that activities "could not constitute infringement if they had been undertaken to develop information reasonably related to the development and submission of information necessary to obtain regulatory approval under the [Food, Drug, and Cosmetic Act]." *Id.* at 664. The Court explained that "the [Hatch-Waxman] Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval." *Id.* at 669. The first "distortion" was the exhaustion of patent life while the patentee was obtaining regulatory approval, by procedures that usually consumed several years. The second distortion was that would-be competitors after patent expiration experienced delay in market entry while obtaining regulatory approval for their generic counterparts. The Hatch-Waxman Act remedied both distortions, striking a careful balance that is embodied in the statute and reflected in precedent.

In *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005) the Court again analyzed the statutory purpose, and explained that "§271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval . . . ." The Court held that preclinical research, whether or not ultimately included in a submission to the Food and Drug Administration, is exempted from infringement by §271(e)(1) "as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND [investigational new drug application] or NDA [new drug application].'" *Id.* at 208 (quoting Brief for United States as *Amicus Curiae* 23). In contrast, the Biogen and Glaxo activities charged with infringement are not related to producing information for an IND or NDA, and are not a "phase of research" possibly leading to marketing approval. *Merck v. Integra* does not provide a §271(e)(1) safe harbor for these activities.

Extensive precedent recites the purpose of §271(e)(1) to facilitate market entry upon patent expiration. *See, e.g.*, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) ("[§271(e)(1)] enabled generic manufacturers to test and seek approval to market during the patent term"); *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008) (examining for purposes of the exemption whether the infringer is "seeking FDA approval for a product in order to enter the market to compete with patentees."). There is no dispute as to the statutory purpose, and no contrary precedent.[4]

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[4] Our colleague in dissent strays from statute and precedent, in arguing that any activity by any entity concerning any adversely patented product or method is exempted from infringement by §271(e)(1), provided only that the information obtained is "reasonably related to submitting *any* information under the FDCA," Diss. Op.

The court erred in its application of §271(e)(1) to the activities of Biogen and GlaxoSmithKline in providing vaccines, in advising on immunization schedules, and in reporting any adverse vaccine effects to the FDA. The judgment of noninfringement based on the safe-harbor of §271(e)(1) is vacated.

C. Study of the Classen Information

Classen's position in the district court appears to have been that the Classen claims are infringed if the subject thereof is the subject of study, analysis, verification, or other scientific inquiry. As the district court remarked, Classen's view of its claims appears to have been that they covered "thinking" about their subject matter. That is, of course, incorrect. The information in patents is added to the store of knowledge with the publication/issuance of the patent. An important purpose of the system of patents is to negate secrecy, and to provide otherwise unknown knowledge to the interested public. As the Court stated in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 142 (2001): "The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'" (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)). In turn, the subject matter of patents may be investigated and verified and elaborated; the technological/scientific contribution to knowledge is not insulated from analysis, study, and experimentation for the twenty years until patent expiration.

This *quid pro quo* is fundamental to patent systems. The statutory requirements of description, enablement, and best mode, implement this policy, for these require-

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at 17 (emphasis in dissent), "including information regarding post-approval uses." *Id.* Such a massive enlargement of the statutory exemption is incorrect.

ments facilitate understanding and elaboration of the inventor's contribution. Were such information prohibited from study until patent expiration, not only would the advance of science be slowed, but the design-around of patented subject matter would be inhibited, if not excluded, if a new design could not be derived from study of the old. Justice Story commented in *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600), that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical[5] experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." Such use of the information in the patent is not a violation of the patent, whereas "the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right." *Id.*

Our colleague in dissent argues that the Classen claims "preempt[] the field of study and prevents any investigation into any immunogen, known or unknown, and to any disease." Diss. Op. at 8. Study of the information in patents is not preempted, whether that information is broadly claimed, as in Classen's "representative" claims, or more narrowly claimed, as in other Classen claims. A pioneering invention, that meets the substantive criteria of patentability, may indeed warrant broad scope. Breadth does not negative patent eligibility, although it may not meet the conditions of patentability. Nor does breadth preclude investigation by others. To the contrary, a fundamental purpose of patenting is to provide knowledge, to achieve further advance. The dissent's "absurd" examples are indeed absurd.

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[5] "Natural philosophy" was the term for "science" in the usage of that era.

The district court reported that Classen charges the defendants with infringement based on their participation in studies "to evaluate suggested associations between childhood vaccinations, particularly against hepatitis B and Haemophilus influenza . . . and risk of developing type 1 diabetes; and to determine whether timing of vaccination influences risk." *Classen,* 381 F. Supp. 2d at 455 (quoting Am. Compl. ¶7). The district court accepted the premise that such activities could be infringing, in deciding the defendants' motions for summary judgment. Should the question arise on remand, the court may consider whether such a scientific investigation of the Classen position is subject to preclusion by the patentee, or is permissible under patent principles.

SUMMARY

The district court's holding of ineligibility for patenting under §101 is reversed as to the claims of the '139 and '739 patents, and affirmed as to the '283 patent. The judgment of non-infringement is affirmed as to Merck, and is vacated as to Biogen and GlaxoSmithKline insofar as based on §271(e)(1). Other claims, counterclaims, and defenses raised by complaint and answer were not decided by summary judgment, and are not before us on this appeal. We remand for appropriate further proceedings.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

CLASSEN IMMUNOTHERAPIES, INC.,
Plaintiff-Appellant,

v.

BIOGEN IDEC,
Defendant-Appellee,

and

GLAXOSMITHKLINE,
Defendant-Appellee,

and

MERCK & CO., INC.,
Defendant-Cross-Appellant,

and

CHIRON CORPORATION, KAISER-PERMANENTE, INC., KAISER PERMANENTE VENTURES, KAISER PERMANENTE INTERNATIONAL, KAISER PERMANENTE INSURANCE COMPANY, THE PERMANENTE FEDERATION, LLC, THE PERMANENTE COMPANY, LLC, THE PERMANENTE FOUNDATION, THE PERMANENTE MEDICAL GROUP, INC., KAISER FOUNDATION HOSPITALS, KAISER FOUNDATION ADDED CHOICE HEALTH PLAN, INC., AND KAISER FOUNDATION HEALTH PLAN INC.,
Defendants.

2006-1634, -1649

Appeal from the United States District Court for the District of Maryland in Case No. 04-CV-2607, Judge William D. Quarles, Jr.

RADER, *Chief Judge*, additional views, joined by PAULINE NEWMAN, *Circuit Judge*.

In the last several years, this court has confronted a rising number of challenges under 35 U.S.C. § 101. The language of § 101 is very broad. Nevertheless, litigants continue to urge this court to impose limitations not present in the statute. Subject matter eligibility under section 101 has become the "substantive due process" of patent law – except that reading non-procedural requirements into the constitutional word "process" has more historical and contextual support than reading abstractness into the statutory word "process" because Title 35 already contains ample protections against vague claims. *See* 35 U.S.C. § 112. Indeed it is difficult to "invent" any category of subject matter that does not fit within the four classes acknowledged by Title 35: process, machine, [article of] manufacture, or composition of matter. This court should decline to accept invitations to restrict subject matter eligibility. In order to highlight some public policy reasons that the statute places few, if any, limits on subject matter eligibility, these additional views are offered.

The patent eligibility doctrine has always had significant unintended implications because patent eligibility is a "coarse filter" that excludes entire areas of human inventiveness from the patent system on the basis of

judge-created standards. For instance, eligibility restrictions usually engender a healthy dose of claim-drafting ingenuity. In almost every instance, patent claim drafters devise new claim forms and language that evade the subject matter exclusions. These evasions, however, add to the cost and complexity of the patent system and may cause technology research to shift to countries where protection is not so difficult or expensive.

The first unintended consequence, claim drafting evasion, has occurred several times in the past. After all, patents require a translation of technology into text, *i.e.*, patent claims. Inevitably the subject matter exclusions of eligibility doctrines depend on the way that claims are drafted. Thus, careful claim drafting or new claim forms can often avoid eligibility restrictions. Eligibility then becomes a game where lawyers learn ingenious ways to recast technology in terms that satisfy eligibility concerns.

Two well-known examples of claim drafting to circumvent eligibility restrictions are the Beauregard claim and the Swiss claim. The Beauregard claim was devised to draft around restrictions on software imposed in *Gottschalk v. Benson*, 409 U.S. 63 (1972). *Benson* denied eligibility to mathematical algorithms, a category broad enough to endanger computer software in general. The Beauregard claim form, however, was for "computer programs embodied in a tangible medium." *In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995). Claims were redrafted so that the intangible computer code in *Benson* instead became an encoded tangible medium in *Beauregard*. *See id.* at 1584 (PTO stating it will treat such claims as patent eligible subject matter); MPEP § 2106 (8th ed. Rev. 8, July 2010) (same).

The Swiss claim was devised to draft around restrictions on medical treatment methods imposed by the

European Patent Convention ("EPC"). EPC, art. 52(4) prohibited patents on the use of a compound X for the treatment of disease Y. The Swiss claim form, however, was for the use of a compound X *for the manufacture* of a medicament for the treatment of disease Y. Claims were redrafted so that the focus became the manufacture of a product instead of the direct treatment using that product. The theory was that the claimed use was restricted to the patentable (initial) industrial use instead of the ineligible (ultimate) therapeutic use. *See Eisai/Second Medical Indication*, G05/83 O.J. (EPO Enlarged Bd. of Appeals 1984) (allowing Swiss claims); Preparatory Documents to Revision of EPC art. 54(5), CA/PL 4/00 (EPO Jan. 24, 2000) (revising the EPC to make clear that such subject matter is patent eligible so that Swiss claims are not needed).

When careful claim drafting or new claim formats avoid eligibility restrictions, the doctrine becomes very hollow. Excluding categories of subject matter from the patent system achieves no substantive improvement in the patent landscape. Yet, these language games impose high costs on patent prosecution and litigation. At the same time, the new games can cheat naïve inventors out of their inventions due to poor claim drafting. Moreover, our national innovation policy takes on characteristics of rewarding gamesmanship.

In addition to gamesmanship, eligibility restrictions increase the expense and difficulty in obtaining a patent. By creating obstacles to patent protection, the real-world impact is to frustrate innovation and drive research funding to more hospitable locations. To be direct, if one nation makes patent protection difficult, it will drive research to another, more accommodating, nation.

Once again, this unintended consequence is not theory but history. In the past, this cause-effect relationship of eligibility restrictions and stifling innovation favored our country in, for example, biotechnology. While Europe imposed eligibility restrictions, the United States embraced strong patent protection. *Compare Diamond v. Chakrabarty*, 447 U.S. 303 (1980) *with* EPC, art. 53 (1973) (exceptions to patentability) *and Harvard/OncoMouse*, T19/901 E.P.O.R. 501 (Technical Bd. of Appeal 3.3.21 1990) (eventually deciding against an outright ban but continuing to impose restrictions).

Europe became known for subjecting such inventions to delays in the patent office, challenges in litigation, increases in cost, and uncertainties in the legal landscape. With those difficulties as a primary contributing factor, investors, corporations, and clinics shifted their research from Europe to the United States. *See* Opinion of European Union Economic and Social Committee, COM (1995) 661 final (July 11, 1996), (recognizing that "Europe is lagging further and further behind the USA," as evidenced by the stark contrast in number of biotech patents, firms, and products; proposing strong patent protection as in the United States to solve "Europe's backwardness"); Council Directive 98/44, 1998 O.J. (L 213) (EC) (finally providing some protection for biotech inventions to counter the trend of companies preferring to patent in the United States). Thus, with some considerable blame on its eligibility doctrines, Europe lost innovation investment to the United States. Our country became the world leader in biotechnology innovation. Nevertheless, the tide can turn against us, too. The effect of eligibility restrictions can send innovation investment elsewhere. Maybe an accommodating clinic in another country would be happy to take the additional funding and opportunity. In sum, judges should tread carefully when imposing new

limits on the protection for categories of human innovation.

These public policy reasons are consistent with the broad language of § 101. As discussed in the majority opinion, section 101 is a general statement of subject matter eligibility. It is a threshold statement that explicitly directs attention to the "conditions and requirements of this title" to qualify for a patent. Thus, patentability, as opposed to subject matter eligibility, depends on the *substantive* conditions in the rest of the title. *See* 35 U.S.C. §§ 102, 103, 112. Many litigation-spawned applications of section 101 do not focus on categories of subject matter that deserve no patent protection but on the particularities of claim language, a question of patentability depending on prior art and adequate disclosure.

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CHIRON CORPORATION, KAISER-PERMANENTE, INC., KAISER PERMANENTE VENTURES, KAISER PERMANENTE INTERNATIONAL, KAISER PERMANENTE INSURANCE COMPANY, THE PERMANENTE FEDERATION, LLC, THE PERMANENTE COMPANY, LLC, THE PERMANENTE FOUNDATION, THE PERMANENTE MEDICAL GROUP, INC., KAISER FOUNDATION HOSPITALS, KAISER FOUNDATION ADDED CHOICE HEALTH PLAN, INC., AND KAISER FOUNDATION HEALTH PLAN INC.,
Defendants.

2006-1634, -1649

Appeal from the United States District Court for the District of Maryland in Case No. 04-CV-2607, Judge William D. Quarles, Jr.

MOORE, *Circuit Judge*, dissenting.

Respectfully, I must dissent from the majority opinion on several grounds. I believe that the claims at issue are to a fundamental scientific principle so basic and abstract as to be unpatentable subject matter and therefore I would affirm the district court's grant of summary judgment of invalidity under § 101. Classen claimed a monopoly over the scientific method itself. I also dissent from the majority's refusal to reach Merck's appeal of the denial of its motion for summary judgment of anticipation. Instead, I would affirm because the district court properly concluded that summary judgment was improper where Merck failed to offer any proof that its prior use included one of the claim elements. Finally, I dissent from the majority's analysis of infringement and its construction of the safe harbor provision under § 271(e)(1) which is contrary to the plain language of the statute and clear Supreme Court guidance.

I. Invalidity under 35 U.S.C. § 101

In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347, 1350 (Fed. Cir. 2010), *cert granted*, __ S. Ct. __ (June 20, 2011), this court held the asserted claims which recited a method comprising administering a

specific drug to a subject and determining the level of the drug in that subject were directed to patentable subject matter. Though both the Prometheus and Classen claims involve administering a drug (immunizing in Classen), the majority concludes that "the analogy [between *Prometheus* and *Classen*] is inapt". Maj. Op. at 22. I agree. The *Prometheus* court explained that administered drugs "do not pass through the body untouched without affecting it," thus "the human body necessarily undergoes a transformation." 628 F.3d at 1356. The *Prometheus* court did not stop its analysis at the generality of the transformation concept. In a detailed comparison to *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989), the *Prometheus* court concluded that the transformative steps in the claims were not merely data gathering steps or insignificant post-solution activity. Finally, the *Prometheus* court concluded that the claims, which were drawn to the administration of specific drugs providing 6-thioguanine to a subject and then measuring specific metabolites, do not preempt broadly the use of any natural correlation, but rather recite specific treatment steps with specific drugs. 628 F.3d at 1355. None of this analysis exists in the majority opinion here in *Classen*. There is no consideration of the extent of preemption by these staggeringly broad and abstract claims.

The Classen claims are not directed to any specific treatment steps or drugs or even any specific chronic immune disorder. The majority concludes that the '283 patent claims are not directed to patentable subject matter, but that the claims of the '139 and '739 patents are directed to patentable subject matter. With all due respect to the majority, I see no distinction between the '283 claims and '139 and '739 claims which warrants differing treatment. Moreover, I am troubled by the majority's conclusion that the '139 and '739 patent claims are directed to patentable subject matter without any analysis of the staggering

breadth of the claims and the preemption issues inherent in claims directed to such fundamental principles.

Claim 1 of the '283 patent was designated as representative:

> 1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

This claim requires two steps: (1) immunizing a group of mammals according to a schedule and then (2) comparing the incidence of chronic immune mediated disorder in the group to a control group.[1]

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[1] I am perplexed by the majority's suggestion that this claim "is directed to the single step of reviewing the effects of known immunization schedules," Maj. Op. at 20, as the claim clearly requires *immunizing mammals* and then comparing the results to the known group. Moreover, the majority unfairly mischaracterizes Classen's arguments regarding the '283 patent. While Classen says "the claims of the patents in suit," it is clear from the context that Classen is referring only to the comparison step of the '139 and '739 patents not requiring clinical trials. As that paragraph explains, the claims being discussed [the '139 and '739 claims] contain the two steps of "Step (I) screening" and "step (II)" immunizing. Moreover, the preceding paragraph clearly demonstrates his claim is that "neither the '139 nor

Claim 1 of the '739 patent (which is being treated as representative of the '139 and '739 patents) states:

> 1. A method of immunizing a mammalian subject which comprises:
>
> (I) screening a plurality of immunization schedules, by
>
> (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and
>
> (b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which

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the '739 patents require actual participation in conducting a study." Classen Br. 40. When Classen actually references the '283 patent, he correctly describes the '283 claims as requiring "two method steps: (I) immunization and (II) comparison." Classen Br. 7. The '283 patent claim clearly and unequivocally requires the physical act of immunization and it is unfair of the majority to analyze the claim for § 101 purposes as though it did not have that step.

> one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),
> (II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

This claim requires two steps: (1) compare the incidence of chronic immune mediated disease in two groups of mammals who were immunized according to different schedules and then (2) immunize a mammal according to the lower risk schedule. There is virtually no difference between these two claims for the purposes of our § 101 analysis. One involves immunizing and then comparing ('283 patent); the other comparing then immunizing ('739 patent).

While I confess the precise line to be drawn between patentable subject matter and abstract idea is quite elusive, at least for me, this case is not even close. In the '283 patent, Classen claims the scientific method as applied to the field of immunization. No limitations exist on the type of drug to immunize with, the schedules that should be used for the immunization, the type of chronic immune disorder to look for, or any limitation on the control group. It is hard

to imagine broader claims. It is harder to imagine a more conceptually abstract claim in the immunization area. Classen's claims are directed to a thought apart from any concrete realities, specific objects or actual instances. This is very much like patenting $E=mc^2$. Compare any two schedules to determine which one has fewer instances of immune disorders. Compare two substances to determine which one tastes sweeter. Compare two cups of coffee to determine which one is stronger. Actually these examples are more concrete than the Classen claims in that I tell you what to look for – sweetness or strength. The Classen claims do not even specify which immune disorder should be studied. Likewise the representative claim from the '139 and '739 patents specifies no specific immune disease, drug, or schedule. These claims cover any kind of comparison between any two schedules, using any drugs and comparing the incidence of any chronic immune disease. After the user performs this completely abstract mental comparison, then the user should immunize the subject with the drug they choose on the schedule they deem lower risk.

To determine whether a claim is directed to patentable subject matter, we must look to the whole claim. *Diamond v. Diehr*, 450 U.S. 175, 192 (1981). These claims do nothing more than suggest that two immunized groups be compared to determine which one is better. These are exactly the type of "abstract intellectual concepts" that "are the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). Classen cannot escape the fundamental abstractness of his claims by limiting them to a single field of use – immunization – since "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use . . . to a particular technological environment." *Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010) (citations omitted) (internal quotation marks omitted); *id.* at 3231 ("*Flook* established that limiting an ab-

stract idea to one field of use . . . did not make the concept patentable.").

Although "[t]he line between a patentable 'process' and an unpatentable 'principle' is not always clear," *Parker v. Flook*, 437 U.S. 584, 589 (1978), Classen's claims clearly cross that line. That Classen seeks to preempt the field is readily apparent as his claims require only two steps: immunizing and comparing. Of course any researcher seeking to investigate new immunogens or immunization schedules relevant to chronic immune-mediated disorders would infringe. But a doctor might also infringe the '283 patent claim by immunizing a patient and comparing the patient's outcome to another patient's. Or a doctor could infringe the '739 patent claim by comparing well known schedules and then immunizing according to the one he thinks best. A patient might be liable for joint infringement by receiving an immunization, and then wondering why their friend got sick when he got the same immunization. Many other examples, each more absurd than the last, spring to mind, any one of which would result in infringement.

Having discovered a principle – that changing the timing of immunization may change the incidence of chronic immune mediated disorders – Classen now seeks to keep it for himself. In the '283 patent, he accomplishes this goal by claiming the use of the scientific method to study the incidence of chronic immune mediated disorders. This preempts the field of study, and prevents any investigation into any immunogen, known or unknown, and to any disease, known or unknown, over any period of time. Where, as here, a patent preempts an idea, a basic building block of science, within a field of study, the patent in practical effect is a patent on the idea itself. *Gottschalk*, 409 U.S. at 72.

The intent and effect of the Classen claims is clear: to keep others from exploring the same principle. "Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from dismissal of petition). Extending patent protection here would "severely interfere with, or discourage, development and the further spread of useful knowledge itself." *Id.* at 128. To wit, nobody else can search for new immunogens, for use of new immunizations, to treat either existing or currently unknown chronic immune-mediated disorders without infringing.

Classen did not invent the immunological response measured in his claim, and the discovery of this phenomenon alone "cannot support a patent unless there is some other inventive concept in its application." *Flook*, 437 U.S. at 594. Classen's whole '283 patent claim is to the use of the scientific method by immunizing groups and comparing results. The immunization step in the '283 patent is nothing more than a data gathering step necessary to explore the effects of different immunization schedules. Classen's whole '739 patent claim is to compare any two schedules for any drug and choose the one with fewer incidence of any chronic immune disease and then immunize. The immunization step of the '739 patent, like updating the alarm limit in *Parker v. Flook*, 437 U.S. 584 (1978), is nothing more than post-solution activity. As the Supreme Court explained:

> The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to

> almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved could be usefully applied to existing survey techniques.

Id. at 590. Similarly, claim 1 of the '739 patent is not directed to patentable subject matter. The post-solution immunization does not transform the unpatentable principle – that a correlation exists between vaccination schedules and incidence of chronic immune disease – into a patentable process.

"[O]ne can reduce any process to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between [immunization and the chronic immune-mediated disorder] . . . that the researchers uncovered." *Lab. Corp.*, 548 U.S. at 137-38. The fact that the claimed method is both useful and uses tangible tools does not change the ultimate purpose of the claim to monopolize that natural phenomenon and preempt the field of study; nor does the fact that someone must carry out the immunization to trigger the natural response which is subsequently compared to the control group. "Indeed, to use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter." *Id.* at 136.

The claims in this case certainly illustrate the challenge our patent system faces "in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles." *Bilski*, 130 S. Ct.

at 3228. Mr. Classen and inventors like him are not without incentives to innovate in this area. He could, of course, claim a method of treating a chronic immune-mediated disorder by using a new and specific immunization schedule. He could also claim new therapeutic immunogens which were identified as potential compounds of interest. He could even claim specific testing methods to assay and explore his new discovery. But Classen does none of this; instead he claims *the study* of and merely comparing whether the timing of immunization affects chronic immune-mediated disorders. "A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws." *Le Roy v. Tatham*, 14 How. 156, 173 (1853); *cf. O'Reilly v. Morse*, 15 How. 62, 113 (1854) ("[W]hile he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. . . . The court is of opinion that the claim is too broad . . . .").

In the end, Mr. Classen's claims seek to monopolize the process of discovery itself, albeit limited to a single field. Our patent system, however, does not award a monopoly that precludes others from using the basic procedures of scientific investigation to study the same phenomenon. *See Bilski*, 130 S. Ct. at 3253 (Stevens, J., concurring) (Patents on laws of nature, natural phenomena, and abstract ideas "would stifle the very progress that Congress is authorized to promote."). Ultimately, the exceptions to patentable subject matter germane to this case rest on the "fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect." *Flook*, 437 U.S. at 593. When, as here, the claims so clearly offend the consti-

tutional imperative to promote the useful arts, where they preempt all application of a principle or idea, it is entirely appropriate to hold them unpatentable subject matter before reaching anticipation, obviousness, or any other statutory section that might also prove invalidity.

I do not understand the distinction that the majority draws between claim 1 of the '283 patent and claim 1 of the '739 patent. Nor do I understand the test the majority proposes for determining patentability under § 101. In reaching its conclusion that the '739 patent claims are directed to patent eligible subject matter, the majority relies heavily on *Research Corp. Technologies v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010). *Research Corp.* explains that claims "are not likely to be so abstract that they" recite nonstatutory subject matter if they are directed to "inventions with specific applications or improvements to technologies in the marketplace." *Id.* at 869. In my view, the claimed inventions in *Bilski* and *Flook* have specific applications to the marketplace, but those claims nonetheless recite nonstatutory subject matter under § 101. Citing *Research Corp.* the majority holds that if the specified method is "functional and palpable," the claims are drawn to statutory subject matter. Maj. Op. at 17. How do we determine whether any given method or claim is "functional" or "palpable?" Is this a return to the rejected notions of "useful, concrete, and tangible?" The majority concludes that the claims of the '139 and '739 patents "are directed to a specific, tangible application" because they "includ[e] the physical step of immunization on the determined schedule." Maj. Op. at 18. The majority points to nothing else in the claims and does not at all consider how these staggeringly broad claims will preempt the entire immunization field from considering any two schedules prior to immunizing any patient with any drug – clearly a sweepingly broad princi-

ple. I cannot agree that this single physical immunization step makes this principle patentable subject matter.[2]

Tying an abstract idea to a tangible result or a specific field of endeavor does not make the idea any less abstract. *Bilski*, 130 S. Ct. at 3230. "To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection." *Diamond*, 450 U.S. at 192. The scientific method is an abstract idea, fundamental to all scientific inquiry, and must be a tool reserved to all men, regardless of its specific application. No one is entitled to patent using the scientific method to discover a cure for a newly discovered disease – undeniably a tangible result – merely because they discovered the disease itself. Classen's claims readily illustrate that linking a natural phenomenon or abstract idea to a useful or practical result is no barrier for a competent patent drafter attempting to monopolize unpatentable subject matter. I would conclude that the Classen claims are directed to unpatentable subject matter.[3]

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[2] The majority explains the difference between the '283 claim (which it holds is *not* directed to patentable subject matter) and the '139 and '739 patent claims (which it holds are directed to patentable subject matter) as follows: "[Claim 1 of the '283 patent] stands in contrast to the '139 and '739 patent claims, which include the subsequent step of immunization on an optimal schedule." Maj. Op. at 19.

[3] With all due respect to my colleagues, I do not agree with the additional views. First, the additional views improperly criticizes litigants for arguing that abstract ideas are exempt from patent protection. We are bound to follow Supreme Court precedent which clearly and explicitly holds that abstract ideas are *not* eligible for patent protection. *Diamond*, 450 U.S. at 185 ("Excluded from such patent protection are . . . abstract ideas."); *Parker*, 437 U.S. at 589 ("[A]bstract intellectual concepts are not patentable . . . ."). Second, I favor "careful claim drafting" and think it a virtue,

II. Invalidity under 35 U.S.C. § 102

I dissent from the majority's refusal to reach Merck's argument on appeal that it was entitled to summary judgment that the claims were invalid for anticipation. I agree that, in general, a denial of summary judgment standing alone is not immediately appealable. But here Merck properly presented us with an alternative grounds for affirming the district court's summary judgment of invalidity, and this issue was thoroughly briefed below and decided by the district court. There is no basis upon which we could or should simply turn our back and refuse to decide an issue that is squarely before us.

In its motion for summary judgment of invalidity, Merck asserted that Classen's claims were anticipated because a vaccination schedule for the Recombivax HB hepatitis vaccine was already in use before Classen filed his patents. The district court denied Merck's motion for summary judgment of anticipation because Merck proffered no evidence that the correlation between immune-mediate disorders and the vaccine were evaluated as required by the representative claims. As the district court correctly noted,

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not a vice. If § 101 causes the drafting of careful, concrete, specific claims over abstract, conceptual claims, I see no harm. The world will have clear notice of the scope of such patent rights. Finally, in this global age, it is not immediately clear to me why the scope of patent rights should dictate the location of the innovation. Chinese companies do not move to the U.S. to carry out their research when they want a U.S. patent. Regardless, any decision on "national innovation policy" such as what will "frustrate innovation" or "drive research funding" should be left to Congress. We do not have the resources, institutional expertise or the mandate to weigh the competing incentives to innovation. Our job is to take the statute as we find it and apply it to the facts of the case before us.

the '283 patent requires "immunizing a treatment group and comparing incidence of a chronic immune-mediated disorder to that of a control group." *Classen Immunotherapies v. Biogen IDEC*, No. WDQ-04-2607, slip op. at 8 (D. Md. Aug. 16, 2006). As the district court held, Merck did not present any evidence that there was a comparison to a control group to determine the incidence of chronic immune-mediated disorders. All Merck demonstrated was that it was using its Recombivax HB hepatitis vaccination on its 0,1,6 schedule prior to the Classen patents. Even if the court accepted this proposition, Merck does not demonstrate that the rest of the method was performed – there is no evidence of comparison to a control group as required by the claims. Both the '139 and '739 patents similarly "require comparing the incidence of immune-mediated disorders in treatment groups with different vaccination schedules and immunizing patients of a schedule identified as low risk." *Classen*, No. WDQ-04-2607, slip op. at 9. Again, the district court correctly held that Merck offered no evidence that any comparison with different schedules or evaluation of incidence of immune-mediated disorders occurred. Merck's proof was limited to the fact that it was immunizing on the 0,1,6 schedule prior to the Classen patents. This does not prove that it performed the rest of the method – the comparisons which Classen claimed. Accordingly, the district court correctly denied summary judgment. On this record, Merck failed to prove that it had performed all the steps of the method claims and therefore its prior use could not anticipate as a matter of law.

These claims are extremely broad, and Merck may well be able to offer proof of anticipation, but it failed to do so at the summary judgment stage – therefore I would affirm the district court's denial of Merck's summary judgment.

III. Infringement

In this case, the district court dismissed Classen's claims against GlaxoSmithKline (GSK) and Biogen under Rule 12(b)(6), finding that the alleged uses fall into the safe harbor described by 35 U.S.C. § 271(e)(1). The majority concludes that the district court incorrectly interpreted the safe harbor of § 271(e)(1) because, according to the majority, § 271(e)(1) is limited to pre-approval activities. The majority's construction is contrary to the plain language of the statute and Supreme Court precedent. The statute broadly recites that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ." 35 U.S.C. § 271(e)(1). Nowhere does the statute limit the safe harbor to pre-approval uses.

The Supreme Court explored the boundaries of this safe harbor in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), when it reversed this court's narrow interpretation of § 271(e)(1). The Court stated that:

> the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process. As an initial matter, we think it is apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.

Merck, 545 U.S at 202 (emphasis in original). The Court continued, "[t]here is simply no room in the statute for

excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." *Id.* To eliminate any lingering doubts, the Court emphasized yet a third time that "[Congress] exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Id.* at 206 (emphases in original).

While it is true that the Supreme Court decided *Integra* in the context of pre-approval activities, the Court repeatedly underscored the breadth of the statute's text. Accordingly, I conclude that the safe harbor extends to *all* uses that are reasonably related to submitting *any* information under the FDCA, including information regarding post-approval uses.

The majority cites extensively from the legislative history in an attempt to justify its construction. But these citations miss the point entirely. There is no dispute that § 271(e)(1) covers pre-approval studies, as the legislative history indicates. None of the legislative history cited by the majority, nor the cases it references, speak to the question at issue here – whether the statute as enacted also covers post-approval activities. The question is not whether Congress intended to protect pre-approval activity – but whether the enacted legislation covers *more* than just pre-approval activity. The language Congress chose to enact and that was signed into law by the President is plain on its face. There is no "pre-approval" limitation. The statute includes within the safe harbor activity "solely for uses reasonably related to the development and submission of information under a Federal law." 35 U.S.C. § 271(e)(1). This statute could have been written to indicate solely for uses seeking federal approval or solely for pre-approval

uses. It was not. The plain language of this statutory text is broader. Any activity solely for uses reasonably related to the development and submission of information under a Federal law is included in § 271(e)(1).

I agree with the district court's plain language construction of the statute, and I agree that, in this case, the alleged participation by GSK and Biogen in studies evaluating risks associated with different vaccination schedules is reasonably related to their requirement to review and report adverse information to the FDA. *See, e.g.*, 21 C.F.R. § 601.70 (requiring annual progress reports of post-approval studies); 21 C.F.R. § 600.80 (requiring the reporting of post-approval adverse reactions). This conclusion, however, disposes of only some of the allegations against GSK and Biogen. Classen also alleges that GSK and Biogen vaccinated patients according to the patented methods, which I believe is not anchored within the statutory safe harbor.

Specifically, in Counts I, II, and IV, Classen accuses GSK of infringing through "the administration of vaccines according to the patented method[s]." Am. Compl. ¶¶ 27, 35, 51. Thus, in Counts I and II, Classen accuses GSK of screening schedules and then immunizing subjects in accordance with a lower risk schedule. In Count IV, Classen accuses GSK of determining the risk of an immunization schedule by immunizing subjects and then comparing the incidence of a disorder (i.e., an adverse event) to that in a control group. Biogen is similarly accused of "administer[ing] the vaccines according to a [risk-reducing] protocol." Am. Compl. ¶ 6. Although GSK and Biogen might be required to report adverse events that occur as a result of their vaccines, they are not required by law or regulation to perform such post-approval vaccinations in order to generate data. Accordingly, I conclude that these activities are not reasonably related to the development and submission

of data to the FDA and therefore do *not* fall within § 271(e)(1)'s safe harbor exception.

The general administration of drugs or vaccines is not reasonably related to post-approval reporting requirements. For example, while the FDA requires the reporting of post-approval adverse reactions, this does not mean that all commercial uses of the vaccine are "solely for uses reasonably related to the development and submission of information under a Federal law." The fact that GSK or Biogen would have to report to the FDA any adverse reaction after administering a vaccine does not mean the administration itself is noninfringing.

For these reasons, I would vacate the district court's dismissal of counts I, II, and IV against GSK and Biogen because some of the alleged activities do not fall within the safe harbor of § 271(e)(1), and I would remand for further proceedings as to those parties. With respect to the district court's grant of summary judgment of noninfringement to Merck, I agree with the majority's affirmance because Classen failed to provide any record evidence sufficient to create a genuine issue of material fact.