IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED,	)	
Plaintiff,	)	
v.	)	C.A. No. 06-438-GMS
ABRAXIS BIOSCIENCE, INC.,	)	
Defendant.	)	

JOINT CLAIM CHART

Pursuant to the Court's Scheduling Order (D.I. 20), Elan Pharma International Limited and Abraxis Bioscience, Inc. respectfully submit this Joint Claim Chart in preparation for the claim construction hearing scheduled for July 24, 2007 at 10:00 a.m.

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I. U.S. Patent No. 5,399,363 ("'363")

Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
1. Particles **consisting essentially of**[3]	"**consisting essentially of**" means that the claimed particles, which include a "crystalline medicament useful for treating cancer" and "a surface modifier," are essentially free of solvent contamination. **Evidence** "The particles of this invention comprise an anticancer agent." '363 c. 2, ll. 27-28 "The particles of this invention contain an anticancer agent as described above having a surface modifier adsorbed on the surface thereof." '363 c. 3, ll. 55-56 "The crystalline particles described in U.S. Patent Application Serial No. 908,125 are essentially free of solvent contamination." '363 PH[4], Paper No. 7, Declaration of G. Liversidge, p. 2. "It is an advantageous feature that a wide variety of surface modified drug nanoparticles free of unacceptable contamination can be prepared in accordance with this invention." 5,145,684 ("'684")	"**[C]onsisting essentially of**" means the claimed particles are composed only of "crystalline medicament," "surface modifier," and at most trace amounts of solvent or other contaminants. **Evidence** "Claim 1 has been amended consonant with the amendment to the claims in parent U.S. Patent No. 5,145,684 for reasons discussed fully in the parent relating to the § 112 rejection and prior art cited therein. More specifically, claim 1 has been amended to recite minimal and maximal amounts of the crystalline anti-cancer agent and surface modifier present. . . ." (Serial No. 07/908,125, 9/15/93 Amendment, p. 6.) "Claim 1 has also been amended to recite that the drug substance is present in a specific amount, i.e., 99.9-10% by weight based on the total weight of the particle. Support for this amendment can be found on page 12, lines 7-9 of the instant specification." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 9.)

[1] All references to independent claims are meant to include asserted dependent claims as well.
[2] Abraxis reserves the right to argue that any claim term is indefinite, regardless of the construction proposed, if any.
[3] Disputed terms and/or phrases are represented in bold.
[4] "PH" as used herein refers to the prosecution history of the cited patent.

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
	c.2, ll. 63-66 "By 'consisting essentially of' it is meant that the claimed particles are essentially free of solvent contamination and other toxic materials, e.g., monomer or initiator, resulting from solvent precipitation and polymerization methods of particle preparation." '684 PH, Paper No. 10 Amendment dated 11/18/1991, p. 9.	"The surface modifier can be present in an amount of 0.1-90%, preferably 20-60% by weight based on the total weight of the dry particle." (Serial No. 07/647,105, application as filed, p. 12, lines 7-9.) "In addition, the claimed particles consist essentially of the drug substance and the surface modifier. By 'consisting essentially of' it is meant that the claimed particles are essentially free of solvent contamination and other toxic materials, e.g., monomer or initiator, resulting from solvent precipitation and polymerization methods of particle preparation. As discussed further below, solvent contamination is a characteristic of particles prepared by solvent precipitation techniques." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 9.) "The crystalline particles described in U. S. Patent Application Serial No. 908,125 are essentially free of solvent contamination. Such essentially solvent free particles prepared according to the method described in U.S. Patent Application Serial No. 908,125 and parent U.S. Patent No. 5,145,684 provide a significant commercial advantage compared to the solvent contaminated particles prepared according to the teaching of Devissaguet et al and other prior art solvent precipitation techniques such as those described in U.S. Patent No. 4,826,689 of record." (Serial No. 07/908,125, 9/13/1993 Amendment, Rule 132 Declaration by G.

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		Liversidge, signed 9/8/93, p. 2.) "The particles of this invention comprise an anticancer agent. The anticancer agent is present in one or more discrete crystalline phases. The crystalline phase differs from an amorphous, i.e., non-crystalline phase which results from conventional solvent precipitation techniques for the preparation of particles in the submicron size range, such as described in U.S. Pat. No. 4,826,689." ('363 patent, 2:28-34.) "The selection of material for the grinding media is not believed to be critical. However, zirconium oxide, such as 95% ZrO stabilized with magnesia, zirconium silicate, and glass grinding media provide particles having levels of contamination which are believed to be acceptable for the preparation of pharmaceutical compositions." ('363 patent, 6:21-27.) "U.S. Patent No. 4,826,689 discloses a method of making uniformly sized noncrystalline amorphous particles from water-insoluble organic compounds wherein the organic compound is dissolved in an organic solvent. However, solvent precipitation techniques such as described in U.S. Patent No. 4,826,689 for preparing particles tend to provide solvent contaminated particles. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		pharmaceutically acceptable levels for diagnostic imaging. Additionally, amorphous materials and formulations tend to exhibit unacceptably poor stability and/or short shelf-lives." (Serial No. 07/908,125, 10/29/92 Information Disclosure Statement Pursuant to 37 C.F.R. 1.97-1.99, p. 3.) "U.K. Patent Application 2,200,048 discloses pharmaceutical colloidal hydrosols for injection. The hydrosols are formed by a solvent precipitation technique (page 11, lines 8-14), and thus exhibit the problems, e.g., solvent contamination, associated with particles prepared by solvent precipitation techniques such as described in U.S. Patent 4,826,689. U.K. Patent Application 2,200,048 suggests that it is not possible to completely remove the solvent, noting that the suspension contains residual organic solvent after solvent removal in a rotary evaporator (page 11, lines 11-14). There is no suggestion of applicants' claimed particles or method." (Serial No. 07/908,125, 10/29/92 Information Disclosure Statement Pursuant to 37 C.F.R. 1.97-1.99, p. 4-5; Serial No. 07/647,105, Information Disclosure Statement Pursuant to 37 C.F.R. 1.97-1.99 dated 11/18/91, p. 2.) "EPO 275,796 describes the production of colloidally dispersible systems comprising a substance in the form of spherical particles smaller than 500 nm. However, the method involves a

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		precipitation effected by mixing a solution of the substance and a miscible non-solvent for the substance and results in the formation of non-crystalline nanoparticle. Furthermore, precipitation techniques for preparing particles tend to provide particles contaminated with solvents. Such solvents are often toxic and can be very difficult if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical." (Serial No. 07/908,125, 10/29/92 Information Disclosure Statement Pursuant to 37 C.F.R. 1.97-1.99, p. 5.) "Devissaguet et al describe a process for preparing nanocapsules. However, the nanocapsules described by Devissaguet et al are radically different than applicants' particles. The Devissaguet et al nanocapsules feature a wall of film-forming polymer (substance A) and a core (substance B), which can be a medicinal. On the other hand, applicants' claimed particles consist essentially of a crystalline anticancer agent and a non-crosslinked surface modifier adsorbed on the surface thereof. Moreover, the only medicinal containing nanocapsules described by Devissaguet et al are prepared by a precipitation technique, i.e., substance B is first dissolved in a solvent. For example, as illustrated in Example 2 therein, indomethecin (sic) is dissolved in acetone. Such solvent precipitation techniques provide non-crystalline, e.g., amorphous, cores which are

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		contaminated with solvent. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical. On the other hand, applicants' crystalline particles, prepared by wet grinding, a technique entirely different than the technique of Devissaguet et al, are essentially free of solvent contamination." (Serial No. 07/908,125, 9/13/1993 Amendment, p. 4.) "To further evidence the nonobviousness of the claimed particles, applicants' proffer herewith the attached Rule 132 Declaration of Gary G. Liversidge, Ph. D., pointing out that the above-noted differences between the particles of the claimed invention and particles prepared by prior art techniques, such as solvent precipitation techniques, are commercially significant." (Serial No. 07/908,125, 9/13/1993 Amendment, p. 5-6.) "U.S. Patent No. 5,049,322 discloses a solvent precipitation technique for preparing nanocapsules. Solvent precipitation techniques ordinarily result in the formation of noncrystalline or amorphous particles. Particles prepared by solvent precipitation techniques provide particles which are contaminated with solvent. Such solvents are often pharmaceutically unacceptable and can be difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical. This problem is noted in U. K. Patent Application

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		2,200,048 of record which suggests that it is not possible to completely remove solvent by conventional techniques." (Serial No. 07/908,125, 9/13/1993 Amendment, Rule 132 Declaration by G. Liversidge, signed 9/8/93, p. 2.) "However, the particles and methods described by Violante are radically different than the applicants' particles and methods. Violante describes a solvent precipitation technique wherein the organic compound is dissolved in an organic solvent." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 13-14.) "Moreover, applicants' invention provides significant commercial advantages compared to Violante and other prior art solvent precipitation techniques for preparing particles such as those described in EPO 275, 796, and U.K. Patent Application GB 2,220,048. Such solvent precipitation techniques result in the formation of particles contaminated with solvents. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical. This problem is noted in U.K. Patent Application 2 200,048 which suggests that it is not possible to completely remove solvent conventional techniques." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 14-15.)

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		"U.S. Patent 4,826,689 discloses a solvent precipitation technique for preparing amorphous particles. Solvent precipitation techniques ordinarily result in the formation of non-crystalline or amorphous particles. Particles prepared by solvent precipitation techniques provide particles which are contaminated with solvent. Such solvents are often pharmaceutically unacceptable and can be difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical." (Serial No. 07/647,105, 11/18/1991 Amendment, Rule 132 Declaration of Eugene Cooper, signed 11/13/91, p. 2.) "The crystalline particles described in U. S. Patent Application Serial No. 647,105 are essentially free of solvent contamination. Such essentially solvent free particles prepared according to the method described in U.S. Patent Application Serial No. 647,105 provide a significant commercial advantage compared to the solvent contaminated particles prepared according to the teaching of Violante et al and other prior art solvent precipitation techniques such as those described in European Patent Application 275,796 and U.K. Patent Application GB 2,200,048." (Serial No. 07/647,105, 11/18/1991 Amendment, Rule 132 Declaration of Eugene Cooper, signed 11/13/91, p. 2)

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99.9 - 10% by weight of a **crystalline medicament useful in treating cancer** susceptible for treatment with said medicament, said medicament having a solubility in water of less than 10 mg/ml,	**"crystalline medicament useful in treating cancer"** means an anticancer drug as recited in the Markush group of the claim in a nanoparticulate phase different from an amorphous phase. **Evidence** The words of the claim itself, i.e., the Markush group of "medicaments" in the claim, which are useful for treating cancer and generally found as crystalline solids. "More particularly, in accordance with this invention, there are provided particles consisting essentially of crystalline anticancer agent having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain effective average particle size of less than about 1000 nm." '363 c. 1, ll. 49-53 "The invention relates to anticancer agents in the form of particles, to anticancer compositions comprising the particles, and to methods of employing the particles." '363 c. 1, ll. 14-17 **"**The invention is based partly on the discovery that surface modified anticancer nanoparticles exhibit reduced toxicity and/or enhanced efficacy." '363 c. 2, ll. 18-20	"[**C**]**rystalline**" means having a regular arrangement of atoms in a space lattice, as distinguished from amorphous. **Evidence** The words of the claim itself support this construction. "The particles of this invention comprise an anticancer agent. The anticancer agent is present in one or more discrete crystalline phases. The crystalline phase differs from an amorphous, i.e., non-crystalline phase which results from conventional solvent precipitation techniques for the preparation of particles in the submicron size range, such as described in U.S. Pat. No. 4,826,689." ('363 patent, 2:28-34.) "The drug substance exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796 cited above." ('684 patent, 3:33-37.) "The crystalline phase differs from non-crystalline and amorphous phases. The crystalline particles of this invention exhibit improved stability compared to particles containing a drug substance in an amorphous phase." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 9.)

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
	"The particles of this invention comprise an anticancer agent. The anticancer agent is present in one or more discrete crystalline phases. The crystalline phase differs from an amorphous, i.e., non-crystalline phase which results from conventional solvent precipitation techniques for the preparation of particles in the submicron size range, such as described in U.S. Pat. No. 4,826,689." '363 c. 2, ll. 28-34 "The crystalline phase differs from non-crystalline and amorphous phases. The crystalline particles of this invention exhibit improved stability compared to particles containing a drug substance in an amorphous phase." '684 PH, Paper No. 10 Amendment dated 11/18/1991, p. 9 "U.S. Patent No. 4,826,689 discloses a method of making uniformly sized non-crystalline amorphous particles from water-insoluble organic compounds wherein the organic compound is dissolved in an organic solvent. However, solvent precipitation techniques such as described in U.S. Patent No. 4,826,689 for preparing particles tend to provide solvent contaminated particles. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels for diagnostic imaging. Additionally, amorphous materials tend to exhibit unacceptably poor stability and/or short shelf-lives." '363 PH, Paper No. 2, Information	"U.S. Patent No. 4,826,689 discloses a method of making uniformly sized noncrystalline amorphous particles from water-insoluble organic compounds wherein the organic compound is dissolved in an organic solvent. . . . Additionally, amorphous materials and formulations tend to exhibit unacceptably poor stability and/or short shelf-lives." (Serial No. 07/908,125, 10/29/92 Information Disclosure Statement Pursuant to 37 C.F.R. 1.97-1.99, p. 3.) "Dispersible particles consisting essentially of a crystalline anticancer agent having a surface modifier adsorbed on the surface thereof." ('363 patent, abstract.) "More particularly, in accordance with this invention, there are provided particles consisting essentially of a crystalline anticancer agent having a surface modifier adsorbed on the surface thereof..." ('363 patent, 1:48-54.) "Devissaguet et al describe a process for preparing nanocapsules. However, the nanocapsules described by Devissaguet et al are radically different than applicants' particles. The Devissaguet et al nanocapsules feature a wall of film-forming polymer (substance A) and a core (substance B), which can be a medicinal. On the other hand, applicants' claimed particles consist essentially of a crystalline anticancer agent and a

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	Disclosure Statement dated 10/29/1992, p. 3 "U.S. Patent No. 5,049,322 discloses a solvent precipitation technique for preparing nanocapsules. Solvent precipitation techniques ordinarily result in the formation of non-crystalline or amorphous particles. Particles prepared by solvent precipitation techniques provide particles which are contaminated with solvent. Such solvents are often pharmaceutically unacceptable and can be difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical. This problem is noted in U.K. Patent Application 2,200,048 of record which suggests that it is not possible to completely remove solvent by conventional techniques." '363 PH, Paper No. 7, Declaration by G. Liversidge, p. 2 "Another approach, exemplified by the teachings of U.S. Patent No. 4,826,689 and EPO 275,796, involves solvent precipitation techniques wherein a solution of the drug substance is mixed with a miscible non-solvent for the substance. Such techniques have provided non-crystalline, e.g., amorphous particles smaller than 500 nm. However, solvent precipitation techniques provide amorphous particles which are unstable and contaminated with solvents. Such solvents are often toxic and can be very difficult, i[f] not impossible, to adequately remove to	non-crosslinked surface modifier adsorbed on the surface thereof. Moreover, the only medicinal containing nanocapsules described by Devissaguet et al are prepared by a precipitation technique, i.e., substance B is first dissolved in a solvent. For example, as illustrated in Example 2 therein, indomethecin (sic) is dissolved in acetone. Such solvent precipitation techniques provide non-crystalline, e.g., amorphous, cores which are contaminated with solvent. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical. On the other hand, applicants' crystalline particles, prepared by wet grinding, a technique entirely different than the technique of Devissaguet et al, are essentially free of solvent contamination." (Serial No. 07/908,125, 9/15/93 Amendment, p. 4.) "U.S. Patent No. 5,049,322 discloses a solvent precipitation technique for preparing nanocapsules. Solvent precipitation techniques ordinarily result in the formation of noncrystalline or amorphous particles." (Serial No. 07/908,125, 9/13/1993 Amendment, Rule 132 Declaration by G. Liversidge, signed 9/8/93, p. 2.) "Another approach, exemplified by the teachings of U.S. Patent 4,826,689 and EPO 275,796, involves solvent precipitation techniques wherein a solution of the drug substance is mixed with a miscible non-

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	pharmaceutically acceptable levels to be practical." '684 PH, Paper No. 10, Amendment dated 11/18/1991 p. 6.	solvent for the substance. Such techniques have provided non-crystalline, e.g., amorphous particles smaller than 500 nm. However, solvent precipitation techniques provide amorphous particles which are unstable and contaminated with solvents." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 6.) "The Office Action indicates that Violante teaches a crystalline drug substance. However, Violante teaches a solvent precipitation technique for preparing amorphous, noncrystalline particles." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 14.) "U.S. Patent 4,826,689 discloses a solvent precipitation technique for preparing amorphous particles. Solvent precipitation techniques ordinarily result in the formation of non-crystalline or amorphous particles." (Serial No. 07/647,105, 11/18/1991 Amendment, Rule 132 Declaration of Eugene Cooper, signed 11/13/91, p. 2) "**[M]edicament useful in treating cancer**" means a medicine suitable for treating cancer. **Evidence** The words of the claim itself support this construction.

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		"The phrase 'anti-cancer' agent is vague and indefinite as said phrase implies/suggests that said 'phrase is a cancer cure'. The examiner suggests the words 'medicament' or 'drug' be considered as an alternative for use of 'anticancer' in said composition claims." (Serial No. 07/908,125, 12/22/93 Office Action, p. 3.) "The Examiner suggests that the words 'medicament' or 'drug' be considered as an alternative for 'anticancer.' Responsive to the Examiner's suggestion, the claims have been amended to recite that the anticancer agent is a specific medicament useful in treating a cancer susceptible to treatment with such medicament." (Serial No. 07/908,125, 6/22/94 Amendment, p. 3.) "We have discovered that anticancer compositions comprising anticancer agents in the form of surface modified nanoparticles exhibit reduced toxicity and/or enhanced efficacy. . . . In another embodiment of the invention, there is provided a method of treating a mammal comprising administering to the mammal the above-described anticancer composition." ('363 patent, 1:44-60.) "Anticancer compositions comprising the particles exhibit reduced toxicity and/or enhanced efficacy, and can be administered by IV bolus injection." ('363 patent, abstract.)

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		"Applicants' claims are further directed to anticancer compositions comprising such particles and to methods of treating mammals comprising administering the particles, whereby the efficacy of the anticancer agent is enhanced and/or the toxicity of the agent is reduced." (Serial No. 07/908,125, 9/15/93 Amendment, p. 3) "Increasing the therapeutic index, e.g., by reducing toxicity or enhancing efficacy would provide more latitude to physicians in their duty of administering anticancer drugs to patients in need thereof. Consequently, methods to reduce toxicity and/or enhance efficacy of anticancer drugs and thus increase the therapeutic indices of such drugs would be of great value in the treatment of cancers. In addition, poorly water-soluble drugs, such as poorly water-soluble anticancer agents, are not readily injectable via an intravenous (IV) bolus injection. The creation of injectable forms of poorly soluble drugs represents a formidable problem. It would be highly desirable to be able to provide poorly soluble drugs, such as poorly soluble anticancer agents, in an IV bolus injectable form." ('363 patent, 1:26-42.) "Pharmaceutical compositions according to this invention include the particles described above and a pharmaceutically acceptable carrier therefor. Suitable pharmaceutically acceptable carriers are well known to those skilled in the art. These

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		include non-toxic physiologically acceptable carriers, adjuvants or vehicles for parenteral injection, for oral administration in solid or liquid form, for rectal administration, and the like. A method of treating a mammal in accordance with this invention comprises the step of administering to the mammal in need of treatment an effective amount of the above-described pharmaceutical composition. The selected dosage level of the drug substance for treatment is effective to obtain a desired therapeutic response for a particular composition and method of administration. The selected dosage level therefore, depends upon the particular drug substance, the desired therapeutic effect, on the route of administration, on the desired duration of treatment and other factors. . . ." ('363 patent, 7:52-8:5; '684 patent, 7:53-8:3.) "It is a particularly advantageous feature that the anticancer compositions of this invention exhibit reduced toxicity and/or enhanced efficacy as illustrated in the examples that follow. Further, the particles of this invention exhibit prolonged circulation in the blood pool. Moreover, anticancer agents which heretofore could not be administered by injection, when prepared as nanoparticles and formulated in anticancer compositions according to this invention, can be effectively administered by injection, e.g., by an intravenous bolus injection." ('363 patent, 8:6-18.)

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
and having a **non-crosslinked**	**"non-crosslinked"** means that the surface modifier does not chemically react with the anticancer agent or itself. **Evidence** "The surface modifier does not chemically react with the anticancer agent or itself." '363 c. 4, ll. 56-57 "Furthermore, the individually adsorbed molecules of the surface modifier are essentially free of intermolecular cross linkages." '363 c. 4, ll. 57- 59 "This patent describes a crystallized carbohydrate matrix for biologically active substances. However, the carbohydrate polymers are crosslinked." '363 PH, Paper No. 8, Information Disclosure Statement, dated 9/13/1993, p. 2	"**[N]on-crosslinked"** means that the surface modifier molecules are individually adsorbed on the surface of the crystalline medicament and are essentially free of intermolecular crosslinkages between surface modifier molecules. **Evidence** "The surface modifier does not chemically react with . . . itself. Furthermore, the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages." ('363 patent, 4: 56-59; '684 patent, 5:16-19.) "Claim 1 has been amended consonant with the amendment to the claims in parent U.S. Patent No. 5,145,684 for reasons discussed fully in the parent relating to the § 112 rejection and prior art cited therein. More specifically, claim 1 has been amended to recite . . . that the surface modifier is non-crosslinked." (Serial No. 07/908,125, 9/13/1993 Amendment, p. 6.) "This patent describes a crystallized carbohydrate matrix for biologically active substances. However, the carbohydrate polymers are crosslinked." (Serial No. 07/908,125, 9/13/1993 Information Disclosure Statement Pursuant to 37 C.F.R. 1.97- 1.99, p. 2.) "Claim 1 has been further amended to specify that the 'surface modifier' is non-crosslinked." (Serial

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
		No. 07/647,105, 11/18/1991 Amendment, p. 9.) "Motoyama is primarily directed to processes … which involve emulsification steps and/or heating and gelling, i.e., crosslinking, reactions." (Serial No. 07/647,105, 11/18/1991 Amendment, p. 15.)
surface modifier	a "**surface modifier**" is a stabilizing agent capable of hindering the aggregation, flocculation and/or agglomeration of the particles. **Evidence** "The surface modifier is adsorbed on the surface of the anticancer agent in an amount sufficient to maintain an effective average particle size of less than about 1000 nm." '363 c. 4, ll. 53-56 "While applicants do not wish to be bound by theoretical mechanisms, it is believed that the surface modifier hinders the flocculation and/or agglomeration of the particles by functioning as a mechanical or steric barrier between the particles, minimizing the close, interparticle approach necessary for agglomeration and flocculation. Alternatively, if the surface modifier has ionic groups, stabilization by electrostatic repulsion may result." '684 c. 8, ll. 21-29. "It was surprising that stable drug particles of such a small effective average particle size and free of	A "**[S]urface modifier**" means a substance that physically adheres to the surface of the crystalline medicament but does not chemically bond to it, and which modifies the surface properties of the crystalline medicament. **Evidence** "The particles of this invention contain an anticancer agent as described above having a surface modifier adsorbed on the surface thereof. Useful surface modifiers are believed to include those which physically adhere to the surface of the anticancer agent but do not chemically bond to the anticancer agent. Suitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients. Such excipients include various polymers, low molecular weight oligomers, natural products and surfactants. Preferred surface modifiers include nonionic and anionic surfactants. Representative examples of excipients include gelatin, casein, lecithin (phosphatides), gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glyceryl monostearate, cetostearyl alcohol,

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
	unacceptable contamination could be prepared by the method of this invention." '684 c. 8, ll. 29-33 "The particles were stable to flocculation/aggregation in rat plasma." '363 c. 8, ll. 31-32 "Stable pip[o]sulfan nanoparticles were also prepared using bovine serum albumin as the surface modifier." '363 c. 9, ll. 44-45 "Example 5 was repeated except that 1.7 g of etoposide was combined with 1.7 g of PVA and the milling time was 14 days. The final particle size was 310 nm. The particles were stable in acid and plasma." 363 c. 11, ll. 35-38 "Example 8 was repeated except that the PVA was replaced by Pluronic F-108 (BASF). The final particle size was 312 nm. The particles were stable in acid and plasma." '363 c. 11, ll. 41-45 "Etoposide (2%) was milled in sterile water for 7 days. A 1:1 mixture of the milled slurry was prepared with 2% Pluronic F127 solution. The mixture was vortexed before measuring particle size. The final size was 277 nm. The slurry was stable in simulated gastric fluid, PBS (pH 7.4) and rat plasma." '363 c. 11, ll. 48-54 "Studies were conducted by mixing 0.5 mL of the	cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, e.g., macrogol ethers such as cetomacrogol 1000, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, e.g., the commercially available Tweens™, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol (PVA), and polyvinylpyrrolidone (PVP). Most of these excipients are described in detail in the *Handbook of Pharmaceutical Excipients*, published jointly by the American Pharmaceutical Association and The Pharmaceutical Society of Great Britain, the Pharmaceutical Press, 1986. The surface modifiers are commercially available and/or can be prepared by techniques known in the art. Two or more surface modifiers can be used in combination. Particularly preferred surface modifiers include polyvinylpyrrolidone, tyloxapol, polaxomers, such as Pluronic™ F68, F108 and F127, which are block copolymers of ethylene oxide and propylene oxide available from BASF, and poloxamines, such as Tetronic™908 (T908), which is a tetrafunctional block copolymer derived from sequential addition of ethylene oxide and propylene oxide to ethylenediamine available from BASF,

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
	WIN 59075 slurry prepared above with 0.5 mL of 6% surface modifier solutions. The final concentration of the drug was 2.5% and that of the surface modifiers was 3%. The surface modifier stabilized nanosuspensions of WIN 59075 were then treated with either PBS (pH 7.0) or 0.1N HCL (pH 1)." '363 c. 13, ll. 19-26 "30 mL of precleaned zirconium oxide media was transferred to a 60 mL amber jar. To it was added 1 g of transretinoic acid (Sigma), 470 mg of tyloxapol and 15 mL of water. The mixture was milled on a roller mill for 15 days. The final particle size was 140 nm. The nanosuspension was stable when exposed to either rat plasma or simulated gastric fluid." '363 c. 13, ll. 60-68 "This invention is based partly on the discovery that drug particles having an extremely small effective average particle size can be prepared by wet milling in the presence of grinding media in conjunction with a surface modifier, and that such particles are stable and do not appreciably flocculate or agglomerate due to interparticle attractive forces and can be formulated into pharmaceutical compositions exhibiting unexpectedly high bioavailability." '684 c. 3, ll. 16-24	dextran, lecithin, Aerosol OT™ (AOT), which is a dioctyl ester of sodium sulfosuccinic acid, available from American Cyanamid, Duponol™ P, which is a sodium lauryl sulfate, available from DuPont, Triton™ X-200, which is an alkyl aryl polyether sulfonate, available from Rohm and Haas, Tween 20, 40, 60 and 80, which are polyoxyethylene sorbitan fatty acid esters, available from ICI Speciality Chemicals, Span 20, 40, 60 and 80, which are sorbitan esters of fatty acids, Arlacel 20, 40, 60 and 80, which are sorbitan esters of fatty acids, available from Hercules, Inc., Carbowax™ 3550 and 934, which are polyethylene glycols available from Union Carbide, Crodesta™ F-110, which is a mixture of sucrose stearate and sucrose distearate, available from Croda Inc., Crodesta SL-40, which is available from Croda, Inc., hexyldecyl trimethyl ammonium chloride (CTAC), bovine serum albumin and SA90HCO, which is C_{18} H_{37} CH_2 (CON (CH_3) CH_2 (CHOH)$_4$ CH_2 OH)$_2$. Surface modifiers which have been found to be particularly useful include polyvinylpyrrolidone, Pluronic F-108, polyvinyl alcohol and gum acacia. The surface modifier is adsorbed on the surface of the anticancer agent in an amount sufficient to maintain an effective average particle size of less than about 1000 nm. The surface modifier does not chemically react with the anticancer agent or itself." ('363 patent, 3:55-4:57.) "Useful surface modifiers are believed to include

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		those which physically adhere to the surface of the drug substance but do not chemically bond to the drug. Suitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients. Such excipients include various polymers, low molecular weight oligomers, natural products and surfactants. Preferred surface modifiers include nonionic and anionic surfactants. Representative examples of excipients include gelatin, casein, lecithin (phosphatides), gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glyceryl monostearate, cetostearl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, e.g., macrogol ethers such as cetomacrogol 1000, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, e.g., the commercially available Tweens, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethycellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, and polyvinylpyrrolidone (PVP). Most of these excipients are described in detail in the *Handbook of Pharmaceutical Excipients*, published jointly by the American Pharmaceutical Association and The Pharmaceutical Society of Great Britain, the

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		Pharmaceutical Press, 1986, the disclosure of which is hereby incorporated by reference in its entirety. The surface modifiers are commercially available and/or can be prepared by techniques known in the art. Particularly preferred surface modifiers include polyvinyl pyrrolidone, Pluronic F68 and F108, which are block copolymers of ethylene oxide and propylene oxide, Tetronic 908, which is a tetrafunctional block copolymer derived from sequential addition of ethylene oxide and propylene oxide to ethylenediamine, dextran, lecithin, Aerosol OT, which is a dioctyl ester of sodium sulfosuccinic acid, available from American Cyanamid, Duponol P, which is a sodium lauryl sulfate, available from DuPont, Triton X-200, which is an alkyl aryl polyether sulfonate, available from Rohm and Haas, Tween 80, which is a polyoxyethylene sorbitan fatty acid ester, available from ICI Specialty Chemicals, and Carbowax 3350 and 934, which are polyethylene glycols available from Union Carbide. Surface modifiers which have found to be particularly useful include polyvinylpyrrolidone, Pluronic F-68, and lecithin." ('684 patent, 4:30-5:12.)
adsorbed on the surface thereof	"**adsorbed on the surface**" means that the surface modifier physically contacts the surface of the "crystalline medicament useful for treating cancer" and does not chemically react with such medicament.	"**[A]dsorbed on the surface**" means that the surface modifier physically adheres to the surface of the crystalline medicament and does not form a chemical bond with the crystalline medicament.

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
	Evidence "Useful surface modifiers are believed to include those which physically adhere to the surface of the anticancer agent but do not chemically bond to the anticancer agent." '363 c. 3, ll. 57-60 "The surface modifier does not chemically react with the anticancer agent or itself" '363 c. 4, ll. 56-59 "The particles can be reduced in size in the presence of a surface modifier. Alternatively, the particles can be contacted with a surface modifier after attrition." '363 c. 5, ll. 28-31.	**Evidence** "The particles of this invention contain an anticancer agent as described above having a surface modifier adsorbed on the surface thereof. Useful surface modifiers are believed to include those which physically adhere to the surface of the anticancer agent but do not chemically bond to the anticancer agent." ('363 patent, 3:55-60; '684 patent, 4:28-33.) "The surface modifier does not chemically react with the anti-cancer agent or itself." ('363 patent, 4:56-57; Serial No. 07/908,125, Description of Preferred Embodiments, p. 7.)
in an amount of 0.1-90% by weight and **sufficient to maintain an average effective particle size** of less than 1000 nm,	"**sufficient to maintain an average effective particle size"** means an amount of surface modifier that maintains the size of the particles such that at least ninety percent of the particles have a number average particle size of less than 1000 nanometers. **Evidence** "The surface modifier is adsorbed on the surface of the anticancer agent in an amount sufficient to maintain an effective average particle size of less than about 1000 nm." '363 c. 4, ll. 53-56 "While applicants do not wish to be bound by	"**[S]ufficient to maintain an average effective particle size**" means that the particles contain an amount of surface modifier sufficient to maintain the average effective particle size of the particles for an unspecified period of time and under unspecified conditions, wherein the average effective particle size means that at least 90% of the particles have the number average particle size specified in the claim. **Evidence** "As used herein, particle size refers to a number average particle size as measured by conventional particle size measuring techniques well known to those skilled in the art, such as sedimentation field

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
	theoretical mechanisms, it is believed that the surface modifier hinders the flocculation and/or agglomeration of the particles by functioning as a mechanical or steric barrier between the particles, minimizing the close, interparticle approach necessary for agglomeration and flocculation. Alternatively, if the surface modifier has ionic groups, stabilization by electrostatic repulsion may result." '684 c. 8, ll. 21-29 **"**As used herein, particle size refers to a number average particle size as measured by conventional particle size measuring techniques well known to those skilled in the art, such as sedimentation field flow fractionation, photon correlation spectroscopy, or disk centrifugation. By 'effective average particle size of less than about 1000 nm' it is meant that at least 90% of the particles have a number average particle size of less than about 1000 nm when measured by the above-noted techniques." '363 c. 4, l. 60 - c. 5, l. 1	flow fractionation, photon correlation spectroscopy, or disk centrifugation. By 'an effective average particle size of less than about [400 or 1000 nm]' it is meant that at least 90% of the particles have a number average particle size of less than about [400 or 1000 nm] when measured by the above-noted techniques." ('363 patent, 4:60-5:1; '684 patent, 5:20-28.)
wherein said medicament is selected from the group consisting of alkylating agents selected from the group consisting of alkylating agents having a bis-(2-chloroethyl)-amine group, alkylating		

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Claim 1 of '363[1]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[2] and Citations to Intrinsic Evidence
agents having a substituted aziridine group, alkyl sulfonates, and N-alkyl-N-nitrosoureas; antimetabolites; natural products selected from the group consisting of vinca alkaloids, epipophylotoxins, adriamycine, daunomycine, doctinomycine, daunorubicin, doxorubicin, mithramycin, bleomycin, mitomycin, enzymes, biological response modifiers, camptothecin, taxol and retinoids; hormones and antagonists: radiosensitizers; platinum coordination complexes; anthracenediones; and adrenocortical suppressants.		

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Claim 12 of '363[5]	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition[6] and Citations to Intrinsic Evidence
12. The particles of claim 1, wherein said surface modifier is a **surfactant.**	A "**surfactant**" is a stabilizing agent that reduces interfacial tension between or among immiscible substances. **Evidence** "Stabilization by Adsorbed Surfactants--As discussed in Chapter 19, surfactants tend to accumulate at interfaces because of their amphiphilic nature. This process is an oriented physical adsorption." Cited Reference Schott, H., "Colloidal Dispersions," Chapter 20, p. 286 "A surfactant or suspending agent is normally added to the reaction mixture to act as a solubilizing or suspending agent for any water-insoluble active ingredients and as a wetting agent to facilitate dispersion of the final product in water." Cited Reference 4,107,288 to Oppenheim, c. 4, ll. 20-25.	"**[S]urfactant**" means a molecule that consists of two basic parts: a hydrophobic part (a non-polar hydrocarbon chain) and a hydrophilic part (a polar functional group). **Evidence** "Suitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients. Such excipients include various polymers, low molecular weight oligomers, natural products and surfactants. Preferred surface modifiers include nonionic and anionic surfactants." ('363 patent, 3:61-66; '684 patent, 4:34-39.)

[5] All references to independent claims are meant to include asserted dependent claims as well.
[6] Abraxis reserves the right to argue that any claim term is indefinite, regardless of the construction proposed, if any.

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II. U.S. Patent No. 5,834,025 ("'025")

Claim 1 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis's Proposed Definition[7] and Citations to Intrinsic Evidence
A method of administering a nanoparticulate composition to a mammal **without eliciting adverse hemodynamic effects** comprising	**"without eliciting adverse hemodynamic effects**" means that the claimed method of intravenous administration reduces, eliminates, or does not elicit cardiovascular dysfunction, such as a reduction in arterial blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility in species of mammals that are sensitive to hemodynamic effects. **Evidence** The language of the claim itself. "Applicants observed that intravascular administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/[min]." '025 PH, Paper No. 9 Amendment dated 2/4/1998 , p. 4 "We have observed that intravascular administration of [] suspensions to dogs causes significant cardiovascular dysfunction, such as reduction in arterial blood pressure and cardiac	"[**W]ithout eliciting adverse hemodynamic effects**" means that the claimed compositions do not elicit undesired effects on the physical aspects of blood circulation (such as reduction in arterial blood pressure and cardiac function) in substantially all of the mammals to whom the claimed compositions are administered. **Evidence** "Disclosed are methods of intravenous administration of nanoparticulate drug formulations to a mammal to avoid adverse hemodynamic effects." ('025 patent, abstract.) "The present invention is directed to nanoparticulate, liposome, emulsion and polymeric colloidal drug formulations for intravenous administration, the delivery of which to a mammal, reduces/eliminates the adverse physiological effects." ('025 patent, 1:12-16.) "We have observed that intravascular administration of suspensions to dogs causes significant cardiovascular dysfunction, such as

[7] Abraxis reserves the right to argue that any claim term is indefinite, regardless of the construction proposed, if any

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Claim 1 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis's Proposed Definition[7] and Citations to Intrinsic Evidence
	function, including heart rate cardiac output and ventricular contractility." '025 c. 1, ll. 49-52 "It has now been discovered that hemodynamic effects of suspensions can be eliminated or at least substantially reduced by controlling the rate of infusion and/or the concentration of the active drug in the suspensions." '025 c. 1, 61-65 "Also, as used herein, mammal preferably means a dog and other sensitive species including human species." '025 c. 2, ll. 66-67.	reduction in arterial blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility. . . . It has now been discovered that hemodynamic effects of suspensions can be eliminated or at least substantially reduced by controlling the rate of infusion and/or the concentration of the active drug in the suspensions." ('025 patent, 1:48-64.) "The following variables were continuously recorded on a pc-based automated data acquisition system (Modular Instruments, Inc., Malvern, Pa.): Mean arterial blood pressure (MAP;mmHg). Heart rate (HR;min^{-1}). Mean pulmonary arterial blood pressure (PAP; mmHg). Left ventricular systolic blood pressure (LVP_{sys};mmHg). Maximum left ventricular dP/dt (+LV dP/dt mmHg sec^{-1}) Maximum left ventricular dP/dt (-LV dP/dt mmHg sec^{-1}). The following variable[s] were mathematically derived from the above variables and cardiac output (CO; L min^{-1}): Systemic arterial vascular resistance (SVR; calculated as MAP/CO; mmHg L^{-} min). Pulmonary vascular resistance (PVR; calculated as PAP/CO; mmHg L^{-1} min) Stroke volume (SV; calculated as CO/HR.1000; cc)." ('025 patent, 4:3-20.)

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Claim 1 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis's Proposed Definition[7] and Citations to Intrinsic Evidence
		"The present invention is directed to intravenous methods of administering a nanoparticulate composition in which the elicitation of adverse hemodynamic effects are eliminated. Applicants observed that intravascular administration of nanoparticulate suspensions can cause significant cardiovascular dysfunction, such as reduction in arterial blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility…. Applicants unexpectedly discovered that such adverse hemodynamic effects associated with intravenous administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/ml, or by pretreating the patient with an antihistamine." (Serial No. 08/696,754, 2/9/1998 Amendment, p. 4.)
intravenously administering to said mammal an effective amount of a nanoparticulate drug composition at **an infusion rate not exceeding 10 mg/min,**	**"infusion rate not exceeding 10 mg/min"** means intravenously administering the nanoparticles, which are comprised of the "organic drug substance" and the "surface modifier," at a rate not exceeding 10 milligrams per minute.	"**[I]nfusion rate not exceeding 10 mg/min**" means intravenously administering the composition by means of gravity flow, at or below a rate of 10 milligrams per minute of the entire composition, including: (a) the drug, (b) the surface modifier, and (c) the pharmaceutically acceptable carrier.

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Claim 1 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis's Proposed Definition[7] and Citations to Intrinsic Evidence
	Evidence "More particularly, the invention relates to a method of intravenous nanoparticulate, liposome, emulsion and polymeric colloidal drug formulations to a mammal, wherein the rate of infusion and concentration of the drug is controlled." '025 c. 1, ll. 16-20. "Applicants unexpectedly discovered that such adverse hemodynamic effects associated with intravenous administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/[min], or by pretreating the patient with an antihistimine." '025 PH, Paper No. 9 Amendment dated 2/4/1998, p. 4. "'[U]ncoated' polystyrene nanoparticles administered at a dose of 0.1 ml/kg of body weight and a rate of 1 ml/min does not induce hemodynamic effect. However, 'uncoated' nanoparticle drugs cannot be administered safely, since they coagulate/flocculate causing deleterious side effects. Accordingly, active drugs must be surfactant coated to circumvent coagulation/flocculation of the nanoparticles. Hemodynamic effect is associated with the surfactant-particle combination." '025 c. 6, ll.	**Evidence** The words of the claim itself support this construction. Claim 1 of the '025 patent claims a method of administering a nanoparticulate composition: "wherein said drug composition comprises: (a) particles consisting essentially of from about 0.1 to about 99.9% by weight of a crystalline organic drug substance having a solubility in water of less than 10 mg/ml; (b) a surface modifier adsorbed on the surface of the drug substance in an amount of from about 0.1 to about 99.9% by weight and sufficient to maintain an effective average particle size of from about 50 nm to about 1000 nm; and (c) a pharmaceutically acceptable carrier therefor." ('025 patent, 16:56-17:4.) "[I]ntravenously administering to said dog an effective amount of a nanoparticulate drug composition at an infusion rate not exceeding 10 mg/min comprising particles consisting essentially of from about 0.1 to about 99.9% by weight of a crystalline organic drug substance having a solubility in water of less than 10 mg/ml, said drug substance having a surface modifier adsorbed on the surface thereof in an amount of 0.1-99.9% by weight and sufficient to maintain an effective average particle size of

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	54-62	from about 50 to about 1000 nm, and a pharmaceutically acceptable carrier therefor." ('025 patent, 2:11-20.) "Applicants unexpectedly discovered that such adverse hemodynamic effects associated with intravenous administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/ml, or by pretreating the patient with an antihistimine." (Serial No. 08/696,754, 2/9/1998 Amendment, p. 4.) "Moreover, the use of an infusion rate of less than 10 mg/ml is not merely an optimization of an administration variable, as the use of this specific infusion rate results in dramatic, unexpected results, *i.e.*, the reduction or elimination of hemodynamic side effects." (Serial No. 08/696,754, 2/9/1998 Amendment, p. 6.)
wherein said drug composition comprises (a) particles **consisting essentially of**	**"consisting essentially of"** means that the particles, which include a "crystalline organic drug substance" and "a surface modifier," are essentially free of solvent contamination.	"**[C]onsisting essentially of**" means the claimed particles are composed only of a "crystalline organic drug substance," a "surface modifier," and at most a trace amount of solvents or other contaminants that would not change the basic and novel characteristics of the particles.

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Claim 1 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis's Proposed Definition[7] and Citations to Intrinsic Evidence
	Evidence "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." '025 c. 1, ll. 23-24. "The particles of this invention comprise a drug substance. The drug substance exists as a discrete, crystalline phase." '684 c. 1, ll. 32-33 "It is an advantageous feature that a wide variety of surface modified drug nanoparticles free of unacceptable contamination can be prepared in accordance with this invention." '684 c. 2, ll. 63-66	**Evidence** "This is a method of preparing stable dispersions of therapeutic and diagnostic agents in the presence of a surface modifying and colloid stability enhancing surface active agent free of trace of any toxic solvents or solubilized heavy metal impurities by the following procedural steps . . . ." ('025 patent, 14:22-27.) "An advantage of microprecipitation is that unlike milled dispersion, the final product is free of heavy metal contaminants arising from the milling media that must be removed due to their toxicity before product is formulated. A further advantage of the microprecipitation method is that unlike solvent precipitation, the final product is free of any trace of trace solvents that may be toxic and must be removed by expensive treatments prior to final product formulation." ('025 patent, 15:4-12.) "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.) "It is an advantageous feature that a wide variety of surface modified drug nanoparticles free of unacceptable contamination can be prepared in accordance with this invention." ('684 patent, 2:63-66.)

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Claim 1 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis's Proposed Definition[7] and Citations to Intrinsic Evidence
		"EPO 275,796 describes the production of colloidally dispersible systems comprising a substance in the form of spherical particles smaller than 500 nm. However, the method involves a precipitation effected by mixing a solution of the substance and a miscible non-solvent for the substance and results in the formation of non-crystalline nanoparticle. Furthermore, precipitation techniques for preparing particles tend to provide particles contaminated with solvents. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical." ('684 patent, 2:3-14.) "The drug substance exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796 cited above." ('684 patent, 3:33-37.)

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from about 0.1 to about 99.9% by weight of a **crystalline organic drug substance** having a solubility in water of less than 10 mg/ml	**"crystalline organic drug substance"** means a therapeutic or diagnostic agent in a nanoparticulate phase different from an amorphous phase. **Evidence** "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." '025 c. 1, ll 23-24 "The particles comprise a therapeutic or diagnostic agent (therapeutic agents are sometimes referred to as drugs or pharmaceuticals. The diagnostic agent referred to is typically a contrast agent such as an x-ray contrast agent but can also be other diagnostic materials). The therapeutic or diagnostic agent exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796." '025 c. 7, ll. 24-31	"[**C]rystalline**" means having a regular arrangement of atoms in a space lattice, as distinguished from amorphous. **Evidence** "The particles comprise a therapeutic or diagnostic agent (therapeutic agents are sometimes referred to as drugs or pharmaceuticals. The diagnostic agent referred to is typically a contrast agent such as an x-ray contrast agent but can also be other diagnostic materials.) The therapeutic or diagnostic agent exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796." ('025 patent, 7:24-32.) "The present invention will be described particularly in reference to nanoparticulate crystalline drug formulations . . . ." ('025 patent, 1:65-2:3.) "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.) "EPO 275,796 describes the production of colloidally dispersible systems comprising a substance in the form of spherical particles

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		smaller than 500 nm. However, the method involves a precipitation effected by mixing a solution of the substance and a miscible non-solvent for the substance and results in the formation of non-crystalline nanoparticle." ('684 patent, 2:3-9.) "The drug substance exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796 cited above." ('684 patent, 3:33-37.) _____ "**[O]rganic drug substance**" means a crystalline carbon-based therapeutic or diagnostic agent suitable for administration to a mammal. **Evidence** "The particles comprise a therapeutic or diagnostic agent (therapeutic agents are sometimes referred to as drugs or pharmaceuticals. The diagnostic agent referred to is typically a contrast agent such as an x-ray contrast agent but can also be other diagnostic materials.) The therapeutic or diagnostic agent exists as a discrete, crystalline phase. The

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		crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796." ('025 patent, 7:24-32.) "The present invention will be described particularly in reference to nanoparticulate crystalline drug formulations . . . ." ('025 patent, 1:66-67.) "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.) "EPO 275,796 describes the production of colloidally dispersible systems comprising a substance in the form of spherical particles smaller than 500 nm. However, the method involves a precipitation effected by mixing a solution of the substance and a miscible non-solvent for the substance and results in the formation of non-crystalline nanoparticle." ('684 patent, 2:3-9.) "The drug substance exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796 cited above." ('684 patent, 3:33-37.)

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(b) a **surface modifier**	A "**surface modifier**" is a surface active agent or stabilizing agent capable of hindering the aggregation, flocculation and/or agglomeration of the particles. **Evidence** "The surface active agent prevents flocculation or congregation of the nanoparticles." '025 c. 1, ll. 37-38 "Nanoparticles are well known in the prior art, having been described , for example, in U.S. Pat. No. 5,145,684." '025 c. 1, ll. 23-25 "While applicants do not wish to be bound by theoretical mechanisms, it is believed that the surface modifier hinders the flocculation and/or agglomeration of the particles by functioning as a mechanical or steric barrier between the particles, minimizing the close, interparticle approach necessary for agglomeration and flocculation. Alternatively, if the surface modifier has ionic groups, stabilization by electrostatic repulsion may results.." '684 c. 8, ll. 22-29 "It was surprising that stable drug particles of such a small effective average particle size and free of unacceptable contamination could be	"**[S]urface modifier**" means a substance that physically adheres to the surface of the crystalline medicament but does not chemically bond to it, and which modifies the surface properties of the crystalline drug substance. **Evidence** "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.) "Useful surface modifiers are believed to include those which physically adhere to the surface of the drug substance but do not chemically bond to the drug." ('684 patent, 4:30-33.) "Suitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients. Such excipients include various polymers, low molecular weight oligomers, natural products and surfactants. Preferred surface modifiers include nonionic and ionic surfactants. Representative examples of surface modifiers include gelatin, casein, lecithin (phosphatides), gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters,

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	prepared by the method of this invention." '684 c. 8, ll. 29-33	polyoxyethylene alkyl ethers, e.g., macrogol ethers such as cetomacrogol 1000, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, e.g., the commercially available Tweens™, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxy propylcellulose, hydroxypropylmethylcellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, and polyvinylpyrrolidone (PVP). Most of these surface modifiers are known pharmaceutical excipients and are described in detail in the *Handbook of Pharmaceutical Excipients*, published jointly by the American Pharmaceutical Association and The Pharmaceutical Society of Great Britain, the Pharmaceutical Press, 1986. Particularly preferred surface modifiers include polyvinylpyrrolidone, tyloxapol, poloxamers such as Pluronics™ F68 and F108, which are block copolymers of ethylene oxide and propylene oxide, and polyxamines such as Tetronics™ 908 (also known as Poloxamine™ 908), which is a tetrafunctional block copolymer derived from sequential addition of

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		propylene oxide and ethylene oxide to ethylenediamine, available from BASF, dextran, lecithin, dialkylesters of sodium sulfosuccinic acid, such as Aerosol OTs™, which is a dioctyl ester of sodium sulfosuccinic acid, available from American Cyanimid, Duponols™ P, which is a sodium lauryl sulfate, available from DuPont, Tritons™ X-200, which is an alkyl aryl polyether sulfonate, available from Rohn and Haas, Tween™ 20 and Tweens™ 80, which are polyoxyethylene sorbitan fatty acid esters, available from ICI Specialty Chemicals; Carbowaxs™ 3550 and 934, which are polyethylene glycols available from Union Carbide; Crodestas™ F-110, which is a mixture of sucrose stearate and sucrose distearate, available from Croda Inc., Crodestas™ SL-40, which is available from Croda, Inc., and SA9OHCO, which is $C_{18}H_{37}CH_2(CON(CH_3)CH_2(CHOH)_4(CH_2OH)_2$. Surface modifiers which have been found to be particularly useful include Tetronics™ 908, the Tweenss™, Pluronics™ F-68 and polyvinylpyrrolidone. Other useful surface modifiers include: decanoyl-N-methylglucamide; n-decyl β-D-glucopyranoside; n-decyl β-D-maltopyranoside; n-dodecyl β-D-glucopyranoside; n-dodecyl β-D-maltoside; heptanoyl-N-methylglucamide; n-heptyl-β-D-glucopyranoside; n-heptyl β-D-

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		thioglucoside; n-hexyl β-D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl β-D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl-β-D-glucopyranoside; octyl β-D-thioglucopyranoside; and the like. Another useful surface modifier is tyloxapol (a nonionic liquid polymer of the alkyl aryl polyether alcohol type; also known as superinone or triton). This surface modifier is commercially available and/or can be prepared by techniques known in the art. Another preferred surface modifier is p-isononylphenoxypoly(glycidol) also known as Olin-1OG™ or Surfactant 10-G, is commercially available as 1OG™ from Olin Chemicals, Stamford, Conn. Non-Ionic Surface Modifiers. Preferred surface modifiers can be selected from known non-ionic surfactants, including the poloxamines such as Tetronic™ 908 (also known as Poloxanmine™ 908), which is a tetrafunctional block copolymer derived from sequential addition of propylene oxide and ethylene oxide to ethylenediamine, available from BASF, or Tetronic™ 1508 (T-1508), or a polymer of the alkyl aryl polyether alcohol type, such as tyloxapol. The surface modifiers are commercially available and/or can be prepared by techniques known in the art. Two-or more surface modifiers can be used in combination. Auxiliary Surface Modifiers. Particularly

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		preferred auxiliary surface modifiers are those which impart resistance to particle aggregation during sterilization and include dioctylsulfosuccinate (DOSS), polyethylene glycol, glycerol, sodium dodecyl sulfate, dodecyl trimethyl ammonium bromide and a charged phospholipid such as dimyristoyl phophatidyl glycerol. The surface modifiers are commercially available and/or can be prepared by techniques known in the art. Two or more surface modifiers can be used in combination. Block Copolymer Surface Modifiers. One preferred surface modifier is a block copolymer linked to at least one anionic group. The polymers contain at least one, and preferably two, three, four or more anionic groups per molecule. Preferred anionic groups include sulfate, sulfonate, phosphonate, phosphate and carboxylate groups. The anionic groups are covalently attached to the nonionic block copolymer. The nonionic sulfated polymeric surfactant has a molecular weight of 1,000-50,000, preferably 2,000-40,000 and more preferably 3,000-30,000. In preferred embodiments, the polymer comprises at least about 50%, and more preferably, at least about 60% by weight of hydrophilic units, e.g., alkylene oxide units. The reason for this is that the presence of a major weight proportion of hydrophilic units confers aqueous solubility to

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		the polymer. A preferred class of block copolymers useful as surface modifiers herein includes sulfated block copolymers of ethylene oxide and propylene oxide. These block copolymers in an unsulfated form are commercially available as Pluronics™. Specific examples of the unsulfated block copolymers include F68, F108 and F127. Another preferred class of block copolymers useful herein includes tetrafunctional block copolymers derived from sequential addition of ethylene oxide and propylene oxide to ethylene diamine. These polymers, in an unsulfated form, are commercially available as Tetronics™. Another preferred class of surface modifiers contains at least one polyethylene oxide (PEO) block as the hydrophilic portion of the molecule and at least one polybutylene oxide (PBO) block as the hydrophobic portion. Particularly preferred surface modifiers of this class are diblock, triblock, and higher block copolymers of ethylene oxide and butylene oxide, such as are represented, for example, by the following structural formula: [ ] The block copolymers useful herein are known compounds and/or can be readily prepared by techniques well known in the art. Highly preferred surface modifiers include triblock copolymers of the [ ] having molecular weights of 3800 and 5000 which are commercially available from Dow Chemical,

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		Midland, Michigan, and are referred to as B20-3800 and B20-5000. These surface modifiers contain about 80% by weight PEO. In a preferred embodiment, the surface modifier is a triblock polymer having the structure: (chemical structure - see patent image). Q is an anionic group wherein R is H or a metal action such as Na+, K+ and the like, x is 15-700, Y is 5-200 and z is 15-700." ('025 patent, 8:33-10:59.)
adsorbed on the surface of the drug substance	**"adsorbed on the surface"** means that the surface modifier physically contacts the surface of the drug substance and does not chemically react with such drug substance. **Evidence** "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." '025 c. 1, ll. 23-25 "The surface modifier does not chemically react with the drug substance or itself. Furthermore, the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages." '684 c. 5, ll. 16-19	"**[A]dsorbed on the surface**" means that the surface modifier physically adheres to the surface of the crystalline drug substance and does not form a chemical bond with the crystalline drug substance. **Evidence** "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.) "The particles of this invention contain a discrete phase of a drug substance as described above having a surface modifier adsorbed on the surface thereof. Useful surface modifiers are believed to include those which physically adhere to the surface of the drug substance but do not chemically bond to the drug." ('684

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	"The particles can be reduced in size in the presence of a surface modifier. Alternatively, the particles can be contacted with a surface modifier after attrition." '684 c. 2, ll. 54-56	patent, 4:28-33.)
in an amount of from about 0.1 to about 99.9% by weight and **sufficient to maintain an effective average particle size** of from about 50 nm to about 1000 nm; and	**"sufficient to maintain an effective average particle size"** means sufficient surface modifier to maintain the size of the particles at an effective average particle size from about 50 to about 1000 nanometers. **Evidence** "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." '025 c. 1, ll. 23-25 "This invention is based partly on the discovery that drug particles having an extremely small effective average particle size can be prepared by wet milling in the presence of grinding media in conjunction with a surface modifier, and that such particles are stable and do not appreciably flocculate or agglomerate due to interparticle attractive forces and can be formulated into pharmaceutical compositions exhibiting unexpectedly high bioavailability." '684 c. 3, ll. 20-24	**"[S]ufficient to maintain an effective average particle size"** means that the particles contain an amount of surface modifier sufficient to maintain the effective average particle size of the particles for an unspecified period of time and under unspecified conditions, wherein the effective average particle size means that at least 90% of the particles have the weight average particle size specified in the claim. **Evidence** "As used herein, particle size refers to a number average particle size as measured by conventional particle size measuring techniques well known to those skilled in the art, such as sedimentation field flow fractionation, photon correlation spectroscopy, or disk centrifugation. When photon correlation spectroscopy (PCS) is used as the method of particle sizing the average particle diameter is the Z-average particle diameter known to those skilled in the art. By 'an effective average particle size of less than about 1000 nm' it is meant that at least 90% of the particles have a weight average

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	"As used herein, particle size refers to a number average particle size as measured by conventional particle size measuring techniques well known to those skilled in the art, such as sedimentation field flow fractionation, photon correlation spectroscopy, or disk centrifugation. When photon correlation spectroscopy (PCS) is used as the method of particle sizing the average particle diameter is the Z-average particle diameter known to those skilled in the art. By 'an effective average particle size of less than about 1000 nm' it is meant that at least 90% of the particles have a weight average particle size of less than about 1000 nm when measured by the above-noted techniques." '025 c. 15, ll. 33-44	particle size of less than about 1000 nm when measured by the above-noted techniques." ('025 patent, 15:33-44.)
(c) a pharmaceutically acceptable carrier therefor.		

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A method of administering a nanoparticulate composition to a mammal **without eliciting adverse hemodynamic effects** comprising	**"without eliciting adverse hemodynamic effects**" means that the claimed method of intravenous administration reduces, eliminates, or does not elicit cardiovascular dysfunction, such as a reduction in arterial blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility in species of mammals that are sensitive to hemodynamic effects. **Evidence** "We have observed that intravascular administration of suspensions to dogs causes significant cardiovascular dysfunction, such as reduction in arterial blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility." '025 c. 1, ll. 49-52 "It has now been discovered that hemodynamic effects of suspensions can be eliminated or at least substantially reduced by controlling the rate of infusion and/or the concentration of the active drug in the suspensions." '025 c. 1, 61-65	"[**W]ithout eliciting adverse hemodynamic effects**" means that the claimed compositions do not elicit undesired effects on the physical aspects of blood circulation (such as reduction in arterial blood pressure and cardiac function) in substantially all of the mammals to whom the claimed compositions are administered. **Evidence** "Disclosed are methods of intravenous administration of nanoparticulate drug formulations to a mammal to avoid adverse hemodynamic effects." ('025 patent, abstract.) "The present invention is directed to nanoparticulate, liposome, emulsion and polymeric colloidal drug formulations for intravenous administration, the delivery of which to a mammal, reduces/eliminates the adverse physiological effects." ('025 patent, 1:12-16.) "We have observed that intravascular administration of suspensions to dogs causes significant cardiovascular dysfunction, such as reduction in arterial

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	"Also, as used herein, mammal preferably means a dog and other sensitive species including human species." '025 c. 2, ll. 66-67 "Applicants observed that intravascular administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/[min]." '025 PH, Paper No. 9 Amendment 2/4/1998, p. 4	blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility. . . . It has now been discovered that hemodynamic effects of suspensions can be eliminated or at least substantially reduced by controlling the rate of infusion and/or the concentration of the active drug in the suspensions." ('025 patent, 1:48-64.) "The following variables were continuously recorded on a pc-based automated data acquisition system (Modular Instruments, Inc., Malvern, Pa.): Mean arterial blood pressure (MAP;mmHg). Heart rate (HR;min^{-1}). Mean pulmonary arterial blood pressure (PAP; mmHg). Left ventricular systolic blood pressure (LVP_{sys};mmHg). Maximum left ventricular dP/dt (+LV dP/dt mmHg sec^{-1}) Maximum left ventricular dP/dt (-LV dP/dt mmHg sec^{-1}). The following variable[s] were mathematically derived from the above variables and cardiac output (CO; L min^{-1}): Systemic arterial vascular resistance (SVR; calculated as MAP/CO; mmHg L min). Pulmonary vascular resistance (PVR; calculated as PAP/CO; mmHg L^{-1} min) Stroke volume (SV; calculated as

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		CO/HR.1000; cc)." ('025 patent, 4:3-20.) "The present invention is directed to intravenous methods of administering a nanoparticulate composition in which the elicitation of adverse hemodynamic effects are eliminated. Applicants observed that intravascular administration of nanoparticulate suspensions can cause significant cardiovascular dysfunction, such as reduction in arterial blood pressure and cardiac function, including heart rate cardiac output and ventricular contractility…. Applicants unexpectedly discovered that such adverse hemodynamic effects associated with intravenous administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/ml, or by pretreating the patient with an antihistamine." (Serial No. 08/696,754, 2/9/1998 Amendment, p. 4.)

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intravenously administering to said mammal an effective amount of a nanoparticulate drug composition at an **infusion rate not exceeding 10 mg/min**	**"infusion rate not exceeding 10 mg/min"** means intravenously administering the nanoparticles, which are comprised of the "organic drug substance" and the "liposome or colliodal polymeric material" at a rate not exceeding 10 milligrams per minute. **Evidence** "More particularly, the invention relates to a method of intravenous nanoparticulate, liposome, emulsion and polymer colloidal drug formulations to a mammal, wherein the rate of infusion and concentration of the drug is controlled." '025 c. 1, ll. 16-20. "Applicants unexpectedly discovered that such adverse hemodynamic effects associated with intravenous administration of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/[min], or by pretreating the patient with an antihistimine." '025 PH, Paper No. 9 Amendment dated 2/4/1998, p. 4. "'[U]ncoated' polystyrene nanoparticles administered at a dose of 0.1 ml/kg of	"**[I]nfusion rate not exceeding 10 mg/min**" means intravenously administering the composition by means of gravity flow, at or below a rate of 10 milligrams per minute of the entire composition, including: (a) the drug, (b) the liposome or colloidal polymeric material, and (c) the pharmaceutically acceptable carrier. **Evidence** The words of the claim itself support this construction. Claim 13 of the '025 patent claims a method of administering a nanoparticulate composition, wherein said drug composition comprises: (a) particles having an effective average particle size of from about 50 to about 1000 nm and consisting essentially of from about 0.1 to about 99.9% by weight of an crystalline organic drug substance entrapped in from about 99.9 to about 0.1% by weight of liposome or a colloidal polymeric material; and b) a pharmaceutically acceptable carrier therefor. ('025 patent, 18:6-19.) "In a liposome- or colloidal-drug delivery

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	body weight and a rate of 1 ml/min does not induce hemodynamic effect. However, 'uncoated' nanoparticle drugs cannot be administered safely, since they coagulate/flocculate causing deleterious side effects. Accordingly, active drugs must be surfactant coated to circumvent coagulation/flocculation of the nanoparticles. Hemodynamic effect is associated with the surfactant-particle combination." '025 c. 6, ll. 54-62	system, the bioactive drug is entrapped in the liposome or colloidal particles in an amount of from about 0.1 to about 99.9 to about 99.1 to about 0.1% by weight liposome or colloidal particles, such particles having a particle size of less than 1000 mm, and then administered to the patient to be treated." ('025 patent, 2:55-60.) "[I]ntravenously administering to said dog an effective amount of a nanoparticulate drug composition at an infusion rate not exceeding 10 mg/min comprising particles consisting essentially of from about 0.1 to about 99.9% by weight of a crystalline organic drug substance having a solubility in water of less than 10 mg/ml, said drug substance having a surface modifier adsorbed on the surface thereof in an amount of 0.1-99.9% by weight and sufficient to maintain an effective average particle size of from about 50 to about 1000 nm, and a pharmaceutically acceptable carrier therefor." ('025 patent, 2:11-20.) "Applicants unexpectedly discovered that such adverse hemodynamic effects associated with intravenous administration

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U.S. Patent Nos. 5,399,363 & 5,834,025

Claim 13 of '025	Elan Pharma's Proposed Definition and Citations to Intrinsic Evidence	Abraxis Bioscience's Proposed Definition and Citations to Intrinsic Evidence
		of nanoparticulate formulations can be eliminated, or substantially reduced, by maintaining the intravenous infusion rate at less than 10 mg/ml, or by pretreating the patient with an antihistimine." (Serial No. 08/696,754, 2/9/1998 Amendment, p. 4.) "Moreover, the use of an infusion rate of less than 10 mg/ml is not merely an optimization of an administration variable, as the use of this specific infusion rate results in dramatic, unexpected results, *i.e.*, the reduction or elimination of hemodynamic side effects." (Serial No. 08/696,754, 2/9/1998 Amendment, p. 6.)
wherein said drug composition comprises: (a) particles having an effective average particle size of from about 50 to about 1000 nm and **consisting essentially of**	**"consisting essentially of"** means that the particles, which include an "organic drug substance" and "liposome or colloidal polymeric material," are essentially free of solvent contamination. **Evidence** "Nanoparticles are well known in the prior art, having been described , for example, in U.S. Pat. No. 5,145,684."684 c. 3, ll. 32-33.	"**[C]onsisting essentially of**" means the claimed particles are composed only of a "crystalline organic drug substance," a "surface modifier," and at most a trace amount of solvents or other contaminants that would not change the basic and novel characteristics of the particles. **Evidence** "This is a method of preparing stable dispersions of therapeutic and diagnostic agents in the presence of a surface modifying and colloid stability enhancing

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	"It is an advantageous feature that a wide variety of surface modified drug nanoparticles free of unacceptable contamination can be prepared in accordance with this invention." '684 c. 2, ll. 63-66	surface active agent free of trace of any toxic solvents or solubilized heavy metal impurities by the following procedural steps . . . ." ('025 patent, 14:22-27.) "An advantage of microprecipitation is that unlike milled dispersion, the final product is free of heavy metal contaminants arising from the milling media that must be removed due to their toxicity before product is formulated. A further advantage of the microprecipitation method is that unlike solvent precipitation, the final product is free of any trace of trace solvents that may be toxic and must be removed by expensive treatments prior to final product formulation." ('025 patent, 15:4-12.) "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.) "It is an advantageous feature that a wide variety of surface modified drug nanoparticles free of unacceptable contamination can be prepared in accordance with this invention." ('684 patent, 2:63-66.)

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		"EPO 275,796 describes the production of colloidally dispersible systems comprising a substance in the form of spherical particles smaller than 500 nm. However, the method involves a precipitation effected by mixing a solution of the substance and a miscible non-solvent for the substance and results in the formation of non-crystalline nanoparticle. Furthermore, precipitation techniques for preparing particles tend to provide particles contaminated with solvents. Such solvents are often toxic and can be very difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical." ('684 patent, 2:3-14.) "The drug substance exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796 cited above." ('684 patent, 3:33-37.)

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from about 0.1 to about 99.9% by weight of an **organic drug substance**	**"organic drug substance"** means a therapeutic or diagnostic agent. **Evidence** "The particles comprise a therapeutic or diagnostic agent." '025 c. 7, ll. 24-25	"**[O]rganic drug substance**" means a crystalline, carbon-based therapeutic or diagnostic agent suitable for administration to a mammal. **Evidence** "The particles comprise a therapeutic or diagnostic agent (therapeutic agents are sometimes referred to as drugs or pharmaceuticals. The diagnostic agent referred to is typically a contrast agent such as an x-ray contrast agent but can also be other diagnostic materials.) The therapeutic or diagnostic agent exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase which results from precipitation techniques, such as described in EPO 275,796." ('025 patent, 7:24-32.) "The present invention will be described particularly in reference to nanoparticulate crystalline drug formulations . . . ." ('025 patent, 1:65-67.) "Nanoparticles are well known in the prior art, having been described, for example, in U.S. Pat. No. 5,145,684." ('025 patent, 1:23-24.)

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entrapped in from about 99.9 to about 0.1% by weight of liposome or a **colloidal polymeric material;** and	**"colloidal polymeric material"** is a polymeric carrier or vehicle for the organic drug substance capable of forming a suspension or dispersion. **Evidence** "Liposomes, emulsions and colloids when used as carriers for an active drug are also suspensions rather than solutions." '025 c. 1, ll. 45-47	"**[C]olloidal**" means a stable suspension of microscopic particles, size range one nanometer to one micron, dispersed in a continuous medium. "**[P]olymeric**" means of, relating to, or consisting of a polymer. "[**M]aterial**" means of, relating to, or consisting of matter.

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	"Suitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients. Such excipients include various polymers, low molecular weight oligomers, natural products and surfactants." '025 c. 8, ll. 34-37	
(b) a pharmaceutically acceptable carrier therefor.		