EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC,

ORIGINAL

Plaintiffs,

vs. Case No. 04-968-GMS

ALCON, INC., ALCON LABORATORIES, INC., and ALCON RESEARCH LTD.,

Defendants.

VIDEOTAPTED DEPOSITION OF VALENTINO J. STELLA, PhD, a witness, taken on behalf of the Defendants, pursuant to Notice, on the 30th day of November, 2005, at the Eldridge Hotel, 701 Massachusetts, Lawrence, Kansas, before SHARON R. HOEGERL, RMR, CRR, of AAA Court Reporting Company, a Certified Shorthand Reporter of the State of Kansas.

APPEARANCES

For the Plaintiffs:

MR. JONATHAN SINGER
MS. DEANNA J. REICHEL
FISH & RICHARDSON, PC, PA
3300 Dain Rauscher Plaza
60 South Sixth Street
Minneapolis, Minnesota 55402

MR. SINGER: Same objection.

A. On that analysis, again, I looked at the big picture. I didn't only focus on this one set of data, and that's what I answered, okay?

Q. (By Mr. Thomasch) I understand. I can ask you about all the data collectively in the case and we would have 30-minute-long questions and hour-long questions. I am entitled, do you understand, to ask you questions about pieces of it. I'm not suggesting -- nowhere in my question have I suggested that this was your analysis, but do you understand that I'm entitled to ask you questions about the information that was provided to you, whether or not you relied on it?

A. I think I've answered the question to the best of my ability.

Q. Did you given any weight whatsoever in your analysis to Tables 1 and Tables 2?

A. Very little.

Q. To the extent you gave any weight, what was it?

A. I put -- I put my -- the extent of my analysis of data is I emphasized and I very much focused on Tables 5 and 6.

Q. I understand, and I've asked you in your

analysis whether you completely discounted Tables 1 and 2, and my understanding is you didn't completely discount them. You gave them, quote, very little weight; is that right?

A. I gave them little weight except for the data above pH 7.

Q. Which data is that?

A. That's the 7.4 and the 7.6 data; the theoretical 7.4 and 7.6 data.

Q. And what, if anything, did you take from that data in connection with your analysis?

A. Combining that with Tables 5 and 6, I concluded that PVP had a positive effect on solubility.

Q. Did you do a statistical analysis of the values in Table 1 and Table 2 connected with the theoretical pH's of 7.4 and 7.6?

A. I did no analysis. I did plot on a graph in my office the data for 7.4 and 7.6, and the data from Tables 5 and 6.

Q. Did you put all of that data on one plot?

A. Yes.

Q. And did you draw curves?

A. No, I did not.

Q. What did you do with that data?

A. I did a visual inspection.

Q. Did you consider that a reliable analytic technique to compare statistical results?

MR. SINGER: Objection to the form of the question.

A. I'm -- I'm a data person. I collect lots of data. I -- when someone does an analysis, especially a regression analysis, I always like to see the regression line and the data points on the same graph, okay? And so I tell my graduate students don't ever show me any sort of regression analysis without data and the regression line put together, and does the regression line reasonably describe the data. So I'm very much a data visual person. I did not do an analysis or any regression analysis on the data that I just described previously because I just didn't have time to do it.

Q. (By Mr. Thomasch) When did you do this plotting and visual inspection?

A. I did that in the last two weeks.

Q. So that would be subsequent to both your initial report and your rebuttal report?

A. Yes.

Q. Did that visual analysis provide any support for any opinions that you expect to express at

EXHIBIT 7

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VOLUME 11

NUCLEAR MEDICINE AND PHARMACY TO PERMEATION ENHANCEMENT THROUGH SKIN

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TABLE 4 Proposed Limits on Particulate Matter in Ophthalmic Preparations

Particle Size (μm)	Limits Proposed, Particles per mL
≥10	≤50
≥25	≤5
>50	None allowed

Stability

The stability of the active ingredient in an ophthalmic solution depends upon the chemical nature of the active ingredient, pH, manufacturing procedure, type of additives, and type of container. The maintenance of a pH that is consistent with acceptable stability is often in conflict with a pH that would provide optimum corneal penetration of the drug in question and optimum patient acceptance of the product.

The maintenance of stability may also dictate the type of packaging employed. For example, epinephrine salts are sensitive to air oxidation, thereby precluding the use of the air-permeable plastic containers that many patients find convenient to use. Epinephrine-containing formulations typically require antioxidants such as sodium bisulfite or sodium metabisulfite or, more recently, combinations of antioxidants such as ascorbic acid and acetylcysteine, sodium bisulfite and 8-hydroxyquinoline, or isoascorbic acid and polyvinylpyrrolidone [50,52].

pH Adjustment and Buffers

The adjustment of ophthalmic solution pH by the appropriate choice of a buffer is one of the most important formulation considerations. Buffers may be used in an ophthalmic solution for one or more of the following reasons: to maintain the physiologic pH of the tears upon administration in order to minimize tearing and patient discomfort (and in so doing enhance patient compliance); to optimize the therapeutic activity of the active ingredient by altering corneal penetration through changes in the degree of ionization; and to optimize product stability [48,58].

The tear fluid pH is reported to vary between 6.9 and 7.5 during the waking hours of the day [62]. The most common active ingredients found in ophthalmic solutions are acid salts of weak bases which are most stable at an acidic pH. Thus the formulator is often faced with the need to choose a pH which does not compromise the stability of the product but is still acceptable to the patient. The solution to this dilemma is usually maintenance of the product at an acid pH with a buffer of low capacity. Provided the drug itself has a weak buffering effect, for example, the alkaloidal salts, and the volume instilled is small, the tears should be able to rapidly adjust the pH to a value near 7.4, thereby minimizing any discomfort. However, occasionally the drug itself may exert a significant buffering effect (e.g., epinephrine bitartrate) and thus a different salt form (epinephrine hydrochloride) may be necessary [52].

Recently, Ahmed and Chaudhuri [63] illustrated that the pH achieved by the buffer may not be the only factor influencing ocular bioavailability. Using pilocarpine nitrate as a model drug, they instilled solutions buffered at pH 4.0 with equimolar concentrations of acetate, phosphate, or citrate buffers into rabbits eyes and measured the in vivo tear

pH-vs.-time profiles. The ocular bioavailability was assessed from miosis-vs.-time profiles. Analysis of these two profiles indicated that the relative order of efficacy for these buffers, compared to an unbuffered system, was unbuffered > acetate > phosphate > citrate. Their most interesting finding was that the bioavailability of pilocarpine was greater from the acetate buffered formulation than from the phosphate buffered formulation, even though the acetate-containing formulation was more strongly buffered at the pH formulated and caused more tearing. The authors attributed this effect to the high residual buffer capacity of the phosphate buffer, exerting a resistance to pH reequilibration near the pKa of pilocarpine. This study underscores the fact that the time course of lacrimal-fluid pH change (and hence the activity of the active ingredient) may be influenced by both precorneal-fluid dynamics (i.e., the rate of drainage, tear, turnover, and extent of induced lacrimation) and concentration (i.e., buffer capacity) as well as the type of buffer.

Tonicity

Tonicity refers to the osmotic pressure exerted by a solution due to the solutes (drugs, additives, etc.) present. Osmotic pressure is a colligative property and therefore its magnitude depends upon the number of "particles" present in the solution, irrespective of whether they are molecules or ions. Thus a uni-univalent electrolyte such as sodium chloride contributes nearly twice the number of "particles" to the solution as an equimolar concentration of a nonelectrolyte such as glucose. Tears and other body fluids exert an osmotic pressure of 302 to 318 mOsm/kg [62] which is approximately equivalent to that of a 0.9% w/v solution of sodium chloride (normal saline). Tear fluid and Normal Saline are said to be isoosmotic, that is, to have equal osmotic pressure. The term isotonic (equal tone) is commonly used interchangeably with isoosmotic. Strictly speaking, the term isotonic should only be used when referring to two solutions consisting of the same solvent separated by a membrane permeable only to the solvent, that is, a semipermeable membrane. Thus it is possible for two solutions to be isoosmotic but not isotonic if one or more of the solutes present can pass through the membrane separating them. Solutions with osmotic pressures lower than that of normal saline are said to be hypotonic, whereas those with higher osmotic pressures are termed hypertonic [48].

In theory, a hypertonic solution placed in the eye tends to draw solvent (water) from its surroundings in order to dilute the instilled solution. In this case, water flows from the aqueous layer through the cornea to the eye surface. Conversely, a hypotonic solution could result in the passage of water from the site of application through the eye tissues. In this case, the epithelial permeability is increased, allowing water to flow into the cornea, the corneal tissue swells, and drug concentration on the ocular surface is temporarily increased [62]. The result of these stimuli could be an increase in lacrimal secretion and blinking which would rapidly wash the instilled solution out of the eye.

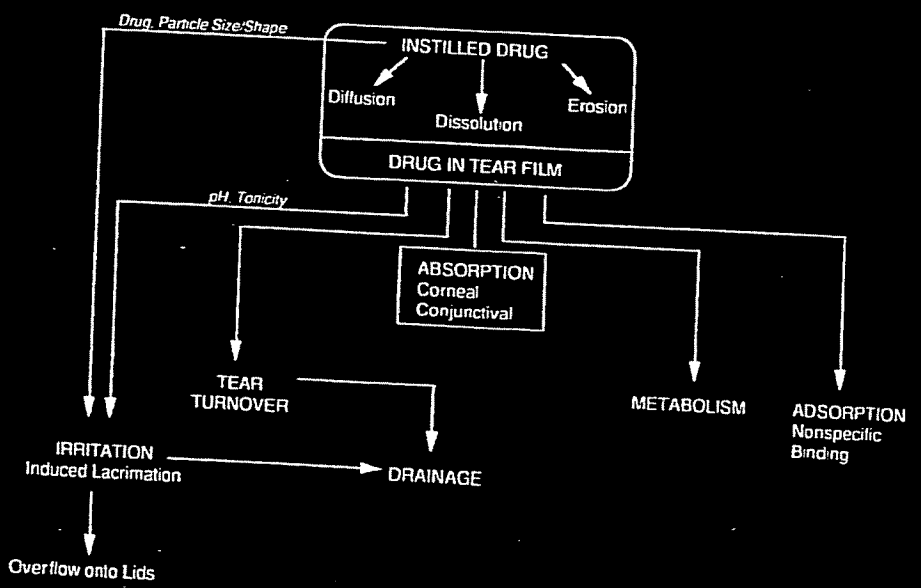
In actual practice, it has been observed that the eye can tolerate a range of osmotic pressure values equivalent to 0.6 to 2.0% sodium chloride without marked discomfort [48]. The normal osmolality of the eye is typically restored within 1 to 2 min of instillation of a nonisotonic solution, depending upon the drop size. Thus the adjustment of tonicity becomes a more important consideration for eye washes where the volume of solution in contact with the ocular surface is increased considerably. Nevertheless, the adjustment of solution tonicity is generally advisable and can be accomplished using a variety of approaches described in detail elsewhere [48,50,51,64,65].

EXHIBIT 8

DRUGS AND THE PHARMACEUTICAL SCIENCES

VOLUME 58

Ophthalmic Drug Delivery Systems



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2
Ocular Anatomy and Physiology Relevant to Ocular Drug Delivery

James C. Robinson *University of Wisconsin, Madison, Wisconsin*

I. INTRODUCTION

The eye is an isolated organ that maintains connection to the rest of the body through its vascular network as well as nerve fibers and selected muscular attachments. As an isolated and highly protected organ, access to specific tissues is seriously constrained by the numerous physiological and protective defense mechanisms that shield the vision pathway from exogenous substances. To design effective drug delivery approaches, it is first necessary to understand the relevant anatomical and physiological constraints that impede or modify ocular drug and vehicle disposition.

The eye is referred to as a globe; however, it is not a true sphere. Indeed, the eye is actually two spheres, one set in the other, as shown in Figure 1. The front sphere is the smaller of the two and is bordered anteriorly by the cornea, whereas the larger posterior sphere is an opaque fibrous shell encased by the sclera (1). The combined weight of both spheres has been given as 6.77–7.5 g, with a volume of approximately 6.5 mL (2). The circumference of the eye is about 75 mm. Along with the rest of the orbital contents, the eye is located within the boney orbital cavity of the head. The eye is approximately 80% of its adult size at birth.

This chapter is intended to provide a description of selective ocular anatomy and physiology that is relevant to ocular drug delivery. Because of space limitations, it is expected that the depth of certain subjects will be insufficient for some readers and they are encouraged to consult cited references.

II. STRUCTURAL SUPPORT

A. The Orbit

The eyes rest in two boney cavities; i.e., the orbits, located on either side of the nose, as shown in Figure 2. The anterior two-thirds of the orbit is roughly the shape of a

well-buffered tear. The turnover of tears is heavily dependent on environmental conditions, such as temperature, relative humidity, and wind as well as age and the physiological state of the patient.

Eyelid movement is of paramount importance in the continual renewal and reformation of the preocular tear film. Tears from the lacrimal gland do not flow across all external eye tissues but rather flow down to the lid margins and from there to the drainage ducts. Thus, adequate wetting of external eye tissues is accomplished by the sweeping action of the lids which moves the secreted tears across the cornea and conjunctiva. Movement of the lids is thus responsible for moving tears into the collection portion of the lacrimal apparatus as well as the distribution of new tears over the ocular surface (13,14). Drainage of tears and instilled solutions away from the front of the eye is an extremely efficient process; i.e., removal of a 25–50 μL volume of instilled solution in the human is essentially completed at around 90 s.

2. *Biochemistry*

The tear film is a trilaminar structure with each layer distinctive in its own composition (Fig. 7). Beginning with the corneal surface, there is a layer of mucin. Just anterior to this layer is an aqueous phase that makes up the bulk of the tear film, and the outermost layer of the tears is a monolayer of lipid.

The anterior layer of the tear film is made up predominantly of a lipid fraction as well as small amounts of mucin and proteins. Mucus and proteins, although they may be surface active, do not retard evaporation. Lipids do, however, reduce evaporation to about 10% of that found in other fluid systems without such a surface layer. The lipids secreted by the tarsal glands along the eyelid margins are neutral oils (4%), phospholipids (16%), sterol ester fractions (32%), mixed waxes (35%), and other lipids (13%) (15,16). The surface-active compounds present in conjunctival mucus facilitate the spreading of tears across precorneal tissues as well as movement of tarsal gland lipids over the surface of the tear film.

The middle layer of the tear film constitutes about 98% of this trilaminar film. This layer is composed mainly of water, electrolytes, and various proteins. The osmotic pressure of the tear film is ~311–350 mOsm in normal eyes and is regulated by the principal inorganic ions Na^+, K^+, Cl^-, HCO_3^-, and proteins (17). The osmotic pressure of tears is slightly higher than blood owing to constant evaporation of the tear film. Under basal conditions, the oxygen tension in the precorneal tear film varies from 140 to 160 mmHg. A minimal precorneal oxygen tension, which is needed to avoid corneal edema, is ~74 mmHg (18).

The posterior layer of the tear film is a mucin layer, i.e., a glycoprotein, which chemically consists of about one-quarter protein and three-fourths carbohydrate. Conjunctival mucus is a mixture of neutral and acidic mucopolysaccharides which are secreted by the approximately 1.5 million goblet cells located on the conjunctival surface. This secreted mucous contributes stability to the tear film as well as furnishing an attachment for the tear film to the underlying cornea and conjunctiva.

Lysozyme (muramidase), an antimicrobial enzyme, is an important protein component of the tear film (19,20). Lysozyme helps to prevent infectious agents from reaching the blood stream via the conjunctival surface and helps maintain sterile conditions in the front of the eye.

in humans. Saettone et al. (26) showed that soluble, mucoadhesive polyanionic polymers, such as hyaluronic acid, poly(galacturonic acid), mesoglycan (a complex mixture of mucopolysaccharides), carboxymethylchitin, and polyacrylic acid, enhanced the ocular absorption of pilocarpine more so than poly(vinyl alcohol) of equivalent viscosity. Similar favorable effects with hyaluronic acid over hydroxypropylmethylcellulose and polyacrylic acid (Carbopol 934P) over poly(vinyl alcohol) have been reported by Camber et al. (27) and Davies et al. (28). Cyanoacrylate block copolymer, another mucoadhesive polymer, has also been found to improve the ocular absorption of pilocarpine by 53% (29).

3. *pH and Tonicity*

For stability reasons, most eye drops are formulated at pHs other than pH 7.4. They are, therefore, potentially irritating to the eye, stimulating tear production. Lacrimal gland fluid secretion can be stimulated by reflexes from afferent pathways arising in the cornea, conjunctiva, and optic nerve. In rabbits, lacrimal gland fluid stimulated by ocular surface reflexes was 3.0 ± 0.5 μL/10 min as compared with a baseline level of 1.0 ± 0.2 mL/10 min. There was a concomitant rise in the protein concentration in tears (30), which could affect the amount of free drug available for corneal absorption. Conrad et al. (31) reported that alkaline pHs induced greater lacrimation than acidic pHs in the albino rabbit. This is consistent with the lower buffer capacity of tears in the basic than in the acidic range (32,33). Since tears are poorly buffered (32), a strategy to minimize the impact of induced lacrimation is to use the most dilute buffer possible; i.e., to keep the tonicity low. By progressively reducing the buffer concentration of a pH 4.5 citrate buffer from 0.11 M to zero, Mitra and Mikkelson (34) observed a fivefold increase in the ocular bioavailability of pilocarpine. In addition to buffer concentration, the buffer type used also affects the absorption efficiency of pilocarpine owing to its effect on the rate at which pH reequilibration will occur (33). Thus, a phosphate buffer (pH 4) which is resistant to pH reequilibration near the pK_a of pilocarpine owing to its high residual buffer capacity, yields a lower bioavailability of pilocarpine than does an acetate buffer, even though its buffer capacity is lower (Fig. 1) (33). Nevertheless, the phosphate buffer is still preferred because the acetate buffer causes excessive lacrimation and may be inherently irritating to the eye.

4. *Drugs*

Drugs that act on the lacrimal gland can affect precorneal fluid dynamics. Examples include epinephrine (35), pilocarpine (36), the local anesthetics tetracaine and proparacaine (37), certain beta-blockers (35), and the tear stimulants currently in development (38). Thus, epinephrine has been shown to accelerate the removal of topically applied liposomes from the conjunctival sac by inducing tear production (39). Induced lacrimation by epinephrine and pilocarpine (and possibly their prodrugs) has also been suggested as a reason for the reduction in ocular absorption of topically applied timolol when used in the same drop with either of the above two drugs (40,41). On the other hand, suppression of tear turnover by the topical instillation of five drops of 0.5% tetracaine has been shown to double the amount of pilocarpine absorbed in the aqueous humor of the albino rabbit eye (37).

B. Drug Binding to Tear Proteins

Although the protein content of tears is much less than that of blood, it is still appreciable and ranges from 0.5% total protein in rabbits to about 0.7% total protein in humans (42). Of

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ASSIGNOR:
OLEJNIK, OREST

DOC DATE: 07/09/2001

ASSIGNOR:
KERSLAKE, EDWARD D.S.

DOC DATE: 07/03/2001

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OREST OLEJNIK
EDWARD D.S. KERSLAKE

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

07/10/01

2. Name and address of receiving party(ies)
Name: ALLERGAN SALES, INC.
Internal Address: PO BOX 19534
Street Address: 2525 DUPONT DRIVE
IRVINE, CA 92612

Additional name(s) & address(es) attached? ☐ Yes ☒ No

3. Nature of conveyance:
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A. Patent Application No.(s)
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Street Address: 2525 DUPONT DRIVE
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6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41)..... $ 40
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AGN0221742

OLEJNIK ET AL 1 Docket No. 17361(AP)

ASSIGNMENT

WHEREAS we, Orest Olejnik of ORANGE COUNTY, CALIFORNIA and Edward D.S. Kenslake of SUFFOLK COUNTY, MASSACHUSETTS (hereinafter referred to as ASSIGNOR), have invented and own a certain invention entitled: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS for which I have executed a provisional application, and non-provisional application claiming priority thereto, for Letters Patent of the United States, said provisional patent application having been filed July 14, 2000 and bearing Serial No. 60/218,200 and said non-provisional application for which application for Letters Patent of the United States has been executed on even date herewith.

WHEREAS: Allergan Sales, Inc., having its principal place of business at 2525 Dupont Drive, Irvine, CA 92612 (hereinafter referred to as ASSIGNEE), is desirous of acquiring the entire interest in, to and under said invention and in, to and under Letters Patent or similar legal protection to be obtained therefor in the United States and in any and all foreign countries.

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN: Be it known that in consideration of the payment by ASSIGNEE TO ASSIGNOR of the sum of One Dollar ($1.00), the receipt of which is hereby acknowledged, and for other good and valuable consideration, ASSIGNOR hereby sells, assigns and transfers to ASSIGNEE the full and exclusive right, title and interest to said invention in the United States and its territorial possessions and in all foreign countries to all Letters Patent or similar legal protection in the United States and its territorial possessions and in any and all foreign countries to be obtained for said invention by said application or any continuation, divisional, renewal, substitute or reissue thereof or any legal equivalent thereof in a foreign country for the full term or terms for which the same may be granted.

ASSIGNOR hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment and sale;

ASSIGNOR further covenants that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said application, said invention and said Letters Patent and legal equivalents in foreign countries as may be known and accessible to ASSIGNOR and will testify as to the same in any interference or litigation related thereto and will promptly execute and deliver to ASSIGNEE or its legal representative any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue and enforce said application, said invention and said Letters Patent and said equivalent thereof in any foreign country which may be necessary or desirable to carry out the purposes thereof.

OLEJNIK ET AL 2 Docket No. 17361(AP)

IN WITNESS WHEREOF, I/We have hereunto set hand and seal this

7/9, 2001.

OREST OLEJNIK

State of CALIFORNIA)
) ss:
County of ORANGE)

On JULY 9, 2001 before me, MARY LOU McNOWN personally appeared OREST OLEJNIK personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person, or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

MARY LOU MCNOWN
Commission # 1229524
Notary Public - California
Orange County
My Comm. Expires Aug 16, 2003

Mary Lou McNown
Notary Public

IN WITNESS WHEREOF, I/We have hereunto set hand and seal this

7/3, 2001.

EDWARD D.S. KERSLAKE

State of MASSACHUSETTS)
) ss:
County of Suffolk)

On July 3, 2001 before me, Maureen Vibert, Notary Public personally appeared Edward D.S. Kerslake personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person, or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

Maureen R Vibert
Notary Public
My Commission Expires: 11/6/2008

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